In the United States Court of Federal Claims

No. 17-1213V
Filed: January 2, 2024

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JODILYN DRUERY,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

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Andrew D. Downing, Downing, Allison & Jorgenson, Phoenix, AZ, for petitioner.

Andrew Henning, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice. Washington, DC, for respondent. With him were **Gabrielle M. Fielding**, Assistant Director, Torts Branch, Civil Division, **Heather L. Pearlman**, Deputy Director, Torts Branch, Civil Division, **C. Salvatore D'Alessio**, Director, Torts Branch, Civil Division, **Brian M. Boynton**, Principal Deputy Assistant Attorney General.

O P I N I O N

HORN, J.

On September 7, 2017, petitioner, Jodilyn Druery, filed a petition for compensation with the National Vaccine Injury Compensation Program (Vaccine Program), under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1–300aa-34 (2018) (Vaccine Act), for an off-Table injury. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii). Petitioner claimed that an October 26, 2016 influenza vaccine caused her to develop medical complications including a "myocardial infarction, resulting in ventricular fibrillation."

On July 11, 2023, Special Master Daniel T. Horner issued a decision finding that the petitioner had not "met her burden of proof" and was not entitled to an award of

[1] This Opinion was issued under seal on January 2, 2024. The parties did not propose any redactions to the January 2, 2024 Opinion, and the court, therefore, issues the Opinion without redactions for public distribution.

compensation. See Druery v. Sec'y of Health & Hum. Servs., No. 17-1213V, 2023 WL 5094088, at *22 (Fed. Cl. Spec. Mstr. July 11, 2023). Subsequently, petitioner filed a Motion for Review in the United States Court of Federal Claims seeking review of the Special Master's decision to deny her claim pursuant to Rule 23 of the Vaccine Rules of the United States Court of Federal Claims (2023) (Vaccine Rules).

FINDINGS OF FACT

Petitioner claims that she was a "healthy woman, who rarely found need for medical attention" before receiving the influenza vaccine, however, prior to her influenza vaccination, petitioner experienced regular migraines. On March 25, 2015, petitioner visited Dr. Daniela Saadia complaining of migraines. Dr. Saadia noted that petitioner began experiencing migraines at the age of 20 and had increased to "12 headache days a month." On October 21, 2015, petitioner visited Dr. Jeffrey Glickman who described petitioner's migraine symptoms as "[s]evere headache starting over the right eye progressing to the back of the skull associated with nausea and light intolerance." (alteration added). Dr. Glickman's diagnosis was "**Intractable chronic migraine without aura and without status migrainosus**."[2] (emphasis in original).

On October 26, 2016, when petitioner was forty-five years old, she received the influenza vaccine from her primary care doctor. During the October 26, 2016 visit, petitioner's records indicate that she had a medical history of migraines, left shoulder pain, and a bone spur. Petitioner's doctor noted during the same visit "[o]ther than that she has been fine. She is trying to exercise and maintain a healthy lifestyle. She has no cardiac pulmonary GI [gastrointestinal] or GU [genitourinary] symptoms." (alterations added).

Following the influenza vaccination, petitioner claims she "began to experience most of the symptoms that were listed on the vaccination side effects sheet they provided her - swelling, hives, headache, arm pain." The following day, October 27, 2016, petitioner alleges she began experiencing "very painful chest pain as well as a tingling in her arms and hands." Petitioner's husband subsequently took her to St. Lucie Medical Center emergency room in Port St. Lucie, Florida upon the pain becoming more intense. The petitioner's chief complaints included "Chest pain, Diaphoresis,[3] and Nausea." (capitalization in original; alteration and footnote added).

Upon further evaluation on October 27, 2016, medical professionals recorded petitioner's blood pressure at 147/103 and her body temperature at 99.0 degrees Fahrenheit. An x-ray of petitioner's chest was negative. In describing petitioner's state at that time, the medical professionals detailed that she was "Awake, Alert, patient is pale, diaphoretic laying in stretcher. Admits to lightheadedness, nausea. Patient appears

[2] Status migrainosus refers to an "episode of migraine that persists for more than 72 hours." https://www.ncbi.nlm.nih.gov/medgen/?term=migrainosus (last visited Feb. 29, 2024).

[3] Diaphoresis is defined as "profuse perspiration artificially induced." https://www.merriam-webster.com/dictionary/diaphoresis (last visited Feb. 29, 2024).

uncomfortable, complaining of chest pain." (capitalization in original; alteration and footnote added). A cardiovascular exam of petitioner was described as "irregularly irregular, tachycardic."[4] In addition, an electrocardiogram (EKG) revealed that petitioner was experiencing "Atrial fibrillation with rapid ventricular response with premature ventricular or aberrantly conducted complexes," "Possible Inferior infarct,"[5] and "Anteroseptal[6] infarct, possibly acute." (alteration and footnote added; capitalization in original).

During the same visit on October 27, 2016, petitioner lost consciousness and required cardiopulmonary resuscitation (CPR). Petitioner was allegedly told by medical professionals that three rounds of CPR were performed. Petitioner was successfully revived. Upon stabilizing petitioner, she was prepped for transfer to Lawnwood Regional Medical Center in Fort Pierce, Florida, to receive a cardiac catheterization. The clinical impression of petitioner's visit to the St. Lucie Medical Center emergency room was "ST elevation myocardial infarction (STEMI) of anterior wall" and "Atrial fibrillation with RVR [Rapid Ventricular Response], Cardiac arrest, Ventricular tachycardia." (capitalization in original; alteration added). Petitioner's medical records from the St. Lucie Medical Center emergency room state: "Patient presented via personal vehicle for chest pain that awoke her from sleep. Patient states the chest pain was 10/10 at onset, sternal, nonradiating. Patient denies a history of similar pain."

On October 28, 2016, Petitioner was admitted to Lawnwood Regional Medical Center. Dr. Anthony Lewis promptly performed a cardiac catheterization on petitioner and did not find any "critical disease" in petitioner's left main artery, left anterior descending artery, circumflex artery, or right coronary artery. Dr. Lewis' notes reflected "Pictures were reviewed also by Dr. Heitman to confirm that there -is no significant coronary disease seen." Petitioner then underwent a transthoracic[7] echocardiogram.[8] This procedure

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[4] Tachycardia is defined as "relatively rapid heart action whether physiological (as after exercise) or pathological." https://www.merriam-webster.com/dictionary/tachycardia (last visited Feb. 29, 2024).

[5] Infarct is defined as "an area of necrosis in a tissue or organ resulting from obstruction of the local circulation by a thrombus or embolus." https://www.merriam-webster.com/dictionary/infarct (last visited Feb. 29, 2024).

[6] Anteroseptal refers to "located in front of a septum and especially the interventricular septum." https://www.merriam-webster.com/medical/anteroseptal (last visited Feb. 29, 2024).

[7] Transthoracic refers to being "done or made by way of the thoracic cavity." https://www.merriam-webster.com/dictionary/transthoracically (last visited Feb. 29, 2024).

[8] An echocardiogram refers to an image made by "ultrasound to examine the structure and functioning of the heart for abnormalities and disease." https://www.merriam-webster.com/dictionary/echocardiography (last visited Feb. 29, 2024).

revealed "Systolic[9] function was mildly to moderately reduced. Ejection fraction was estimated in the range of 45-50%. There was diffuse hypokinesis."[10] (capitalization in original; alteration and footnote added). On October 28, 2016, a computerized tomography angiography (CTA) scan of petitioner's chest was conducted. The impression showed no signs of a pulmonary embolism.

On October 29, 2016, Dr. Lewis stated that "CAD [coronary artery diseases] WITH 90% LAD [left anterior descending] BUT VERY SMALL VESSEL DOUBT THIS IS REASONABLE FOR SCD [sudden cardiac death]." (capitalization in original; alterations added). Dr. Lewis consulted Dr. Dragana Orlovic on October 29, 2016, to assess petitioner's chest pain and rule out the possibility of endocarditis[11] and leukocytosis[12] as the potential causes of the pain. Dr. Orlovic noted that Ms. Druery told Dr. Orlovic that she

> had history of flu vaccine, which she received a couple of days ago. That same night [October 26, 2016] she developed local reaction with redness and some skin changes. The next day, this had resolved. She had flu vaccine in the past and did not have any reaction to them.

(alteration added). Dr. Rolovich's differential diagnosis listed "vascular congestion, viral or infectious pneumonitis."[13]

On October 31, 2016, petitioner underwent a myocardial single-photon emission computerized tomography (SPECT) test that found that "[l]arge defects involving the apex, inferoseptal and anteroseptal[14] walls compatible with multivessel disease."

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[9] Systolic means "a rhythmically recurrent contraction especially the contraction of the heart by which the blood is forced out of the chambers and into the aorta and pulmonary artery." https://www.merriam-webster.com/dictionary/systolic (last visited Feb. 29, 2024).

[10] Hypokinesia is defined as: "Abnormally diminished motor activity." https://www.ncbi.nlm.nih.gov/medgen/39223 (last visited Feb. 29, 2024).

[11] Endocarditis is the "inflammation of the lining of the heart and its valves." https://www.merriam-webster.com/dictionary/endocarditis (last visited Feb. 29, 2024).

[12] Leukocytosis refers to "an increase in the number of white blood cells in the circulating blood." https://www.merriam-webster.com/dictionary/leukocytosis (last visited Feb. 29, 2024).

[13] Pneumonitis refers to "acute or chronic inflammation of the lungs that is characterized especially by cough, shortness of breath, fatigue, and fever, and may result in the development of fibrotic scar tissue when chronic or untreated." https://www.merriam-webster.com/dictionary/pneumonitis (last visited Feb. 29, 2024).

[14] Anteroseptal is defined as "located in front of a septum and especially the interventricular septum https://www.merriam-webster.com/medical/anteroseptal (last visited Feb. 29, 2024). Inferoseptal is defined as relating to the inferior septum of the heart.

(alterations and footnote added). As noted in Special Master Horner's decision: "Petitioner was discharged from LRMC [Lawnwood Regional Medical Center] and admitted to JFK Medical Center [in Port St. Lucie, Florida] on November 2, 2016. Her assessment at discharge listed her previous diagnoses and included 's/p [status post] flu shot reaction.'" Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *6 (last alteration in original).

On November 2, 2016, Dr. Jeffrey Devon assessed petitioner and developed a plan that included petitioner undergo procedure to place an implantable cardioverter-defibrillator and have petitioner evaluated by infectious disease and rheumatology. Dr. Ana Raquel Mateo-Bibeau was consulted to assess "possible myocarditis"[15] and eliminate the possibility of infection in petitioner prior to the procedure. The implantable cardioverter-defibrillator was placed on November 3, 2016.

Petitioner was discharged from JFK Medical Center to her home on November 4, 2016. Petitioner was in stable condition upon discharge and was instructed that she could "Resume Previous Activity As Tolerated." (capitalization in original).

Petitioner returned to Dr. Lewis on December 2, 2016, to establish a care plan and evaluated palpitations that petitioner experienced following the cardioverter-defibrillator implant. During a follow up appointment with Dr. Lewis on March 2, 2017, petitioner complained of daily mild headaches, difficulty sleeping, and diaphoresis. Petitioner also mentioned shortness of breath resulting from flutters in her chest. At that visit, Dr. Lewis diagnosed petitioner with unstable angina[16] and ordered an EKG.

On May 26, 2017, petitioner visited Dr. Glickman for a routine check-up. Dr. Glickman noted that petitioner "feels great," but "She does occasionally get a very short palpitation which gets her worried but her defibrillator has been interrogated and apparently there are no serious arrhythmias." Dr. Glickman also noted that "[f]or a while after her cardiac event she had no migraines but they have recurred. However the frequency is decreased and she's had only 5 in the last 6 months." (alteration added). On August 28, 2017, petitioner visited Dr. Lewis. Petitioner complained of continued chest fluttering. Dr. Lewis maintained petitioner's diagnosis as "unstable angina" and requested another EKG. During a follow up appointment with Dr. Lewis on January 4, 2018, Dr. Lewis noted that petitioner's diagnosis with unstable angina remained unchanged.

On April 4, 2018, petitioner visited Candy Jones, a nurse practitioner who noted petitioner informed the nurse practitioner that petitioner "[a]pparently had MI [myocardial infarction] due to flu shot 2016. Now has defibrillator 11/2016." (alterations added). The nurse practitioner's notes also reflect petitioner "[s]topped having HA [headaches] after

[15] Myocarditis refers to "inflammation of the myocardium," or "the middle muscular layer of the heart wall." https://www.merriam-webster.com/dictionary/myocarditis (last visited Feb. 29, 2024).

[16] Angina refers to "a disease marked by spasmodic attacks of intense suffocative pain." https://www.merriam-webster.com/dictionary/angina (last visited Feb. 29, 2024).

MI, then started coming back." (alterations added). On January 11, 2019, petitioner visited Dr. Darryl Miller. Dr. Miller's notes stated "[i]t is very likely that her cardiac event in 2016 was Takotsubo syndrome,[17] however her wall motion appears to have not recovered. The precipitating event is unclear, however appears to be related to the influenza vaccine." (alterations and footnote added).

On February 14, 2020, more than three years after petitioner's cardiovascular event, petitioner visited St. Lucie Emergency Room in Port St. Lucie, Florida complaining of "defibrillator dysfunction." The notes from the visit state that "[s]he was catheterized after the STEMI which was thought to be due to influenza vaccine reaction secondary to no coronary artery occlusion." (alterations in original). Another record from the visit states "PATIENT SAYS SHE FELT HER DEFRIBILATOR [sic] GO OFF IN HER CHEST DEFIBRILATOR [sic] PUT IN 3 YEARS AGO AFTER REACTION TO FLU SHOT WENT INTO CARDIAC ARREST PER PATIENT." (capitalization in original; alterations added).

Special Master Horner, in his decision, noted that "[s]everal other records are limited to merely recording petitioner's own assertion that her cardiac event was due to her flu vaccination." Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *21 (alteration added).

Procedural History

As noted above, on September 7, 2017, petitioner filed a petition claiming she received an "influenza vaccination within the United States on October 26, 2016 which resulted in cardiac arrest requiring CPR and defibrillation." The petition similarly alleges "Ms. Druery suffered a myocardial infarction, resulting in ventricular fibrillation. CPR was administered and she was defibrillated three times before being revived."

[17] Takotsubo syndrome is defined as:

> Transient left ventricular apical ballooning syndrome or takotsubo cardiomyopathy is characterized by transient regional systolic dysfunction involving the left ventricular apex and/or mid-ventricle in the absence of obstructive coronary disease on coronary angiography. Patients present with an abrupt onset of angina-like chest pain, and have diffuse T-wave inversion, sometimes preceded by ST-segment elevation, and mild cardiac enzyme elevation.

https://www.ncbi.nlm.nih.gov/medgen/?term=Takotsubo+syndrome (last visited Feb. 29, 2024).

The case was initially assigned to Special Master Mindy Michaels Roth and then subsequently reassigned to Special Master Katherine E. Oler.[18] On February 7, 2022, the case was reassigned to Special Master Daniel T. Horner.

During the pendency of petitioner's case, she filed her medical records as exhibits as well as an expert medical opinion by cardiologist Robert Stark, M.D., who concluded that petitioner's "acute MI was caused by coronary endothelial dysfunction that was triggered by an acute phase inflammatory reaction to an influenza immunization." Special Master Horner indicated that

> Dr. Stark explains petitioner's treating cardiologist indicated that petitioner suffered coronary enigma with no evidence of occlusion. Dr. Stark suggests that the only explanation for such an occurrence is systemic inflammation affecting the coronary arteries. He suggests that petitioner's exaggerated immune response to vaccination the day prior, evidenced by her arm swelling, headaches, pain, and malaise, favors this explanation. Further to this, Dr. Stark attributes petitioner's elevated white blood cell count to this inflammation rather than any incurrent viral infection. Additionally, he suggests that the fact that multiple regions of the heart were damaged is evidence the root cause was systemic rather than any simple mechanical blockage.

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *9 (internal references omitted). Special Master Horner additionally observed that "Dr. Stark cites four articles for the proposition that the flu vaccine can cause an acute phase inflammatory response affecting the coronary arteries (Carty et al., Glaser, et al., Liuba, et al., and Ritter, et al.)." Id.

Dr. Stark's expert report asserted that research supports the finding that "influenza vaccine causes an acute phase inflammatory response within 24 hours after immunization." According to Dr. Stark, inflammation can cause "systemic impairment of coronary vessel endothelial function leading to acute cardiovascular events." As noted by Special Master Horner, "Dr. [Athol Winston] Morgan was presented to respond to specific questions posed by the [S]pecial [M]aster after Dr. Stark became unavailable." Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *10 (alterations added). Special Master Horner noted that when

> [a]sked whether it is significant that petitioner had atherosclerotic disease in her small diagonal artery, Dr. Morgan appears to suggest that this may be irrelevant to either Dr. Stark's or Dr. Axelrod's theories, but that it supports a third theory of causation. He opines that "the inflammatory response precipitated endothelial injury leading to clot formation and ultimately occlusion of the artery causing myocardial infarction. The clot

[18] On August 17, 2020, Special Master Oler granted in part petitioner's request for interim fees and costs. See Druery v. Sec'y of Health & Hum. Servs., No. 17-1213V, 2020 WL 5743105, at *5 (Fed. Cl. Spec. Mstr. Aug. 17, 2020).

> then dissolved and moved downstream and, as such, was not visible at the time of the cardiac catheterization."

Id. (internal references omitted; alteration added). Special Master Horner also noted that when

> [a]sked whether a systemic reaction can precipitate Takotsubo syndrome (a condition raised by treating physician, Dr. Miller), Dr. Morgan indicates that it can. However, he does not agree that petitioner suffered Takotsubo syndrome. Takotsubo syndrome is usually benign, resulting in full recovery of myocardial function within days. Asked whether 31 hours post-trigger is an appropriate timeframe for a systemic inflammatory response to occur, Dr. Morgan indicates that he agrees with Dr. Axelrod that the immune response can peak at 24 hours and persist for some time. He opines that 31 hours is "absolutely" within the appropriate timeframe for such a reaction to occur.

Id. at *10-11 (internal references omitted; alteration added).

In addition, petitioner filed an expert report by immunologist David Axelrod, M.D., who stated in his expert report:

> What is set forth below provides a theory of causation between the influenza vaccination and the myocardial infarction and myocardial dysfunction suffered by Jodilyn Druery, based upon peer reviewed scientific papers. We have used studies that involved animal models of human disease. Non-human mammals are not humans. However, animal models of human disease have provided useful information for the understanding, diagnosis and treatment of human disease.
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> Special Master Horner explained in his decision:
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> Dr. Axelrod cites three studies (by Fagnoul, et al., Paddock, et al., and Fountoulaki, et al.) that he indicates show that a subset of patients suffering influenza infection experience myocardial damage and cardiovascular events. Initially, he cites a further study by Rasmussen, et al., which he indicates shows subjects experiencing elevations in certain cytokines following subarachnoid hemorrhage and vasospasm, though vasospasm alone was not associated with increased cytokine levels. However, he also cites three additional studies (by Fassbender et al., Li, et al., and Bowman, et al.) that he asserts show vasospasm to be associated with elevated IL-6, which he opines evidence IL-6 as a significant cause of vasospasm. In any event, Dr. Axelrod indicates the cytokine levels observed by Rasmussen, et al., were lower than the levels observed in a study by Kashiwagi, et al., which observed post-vaccination cytokine responses. He cites three further studies (by Sawurwein-Teisssel, et al., Christian, et al., and Nakayama, et al.) that he indicates show elevated cytokines post-flu vaccination.

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *11 (emphasis in original; internal references and footnotes omitted). In a section of Dr. Axelrod's expert report titled: "**ELIMINATION OF ALTERNATIVE CAUSES**," (capitalization and emphasis in original), Dr. Axelrod stated:

> At the time of Jodilyn Druery's influenza vaccination, she had no evidence of an underlying autoimmune disorder or autoinflammatory disorder (Textbook of Autoinflammation, Chapter 11). Her arthritic back complaints were structural in nature, not inflammatory. She did not have evidence of an active infection The only proinflammatory event experienced by Jodilyn Druery was her influenza vaccination. Jodilyn Druery suffered a myocardial infarction, without evidence of a significant anatomic obstruction of the coronary arteries. I am not a Cardiologist. I must leave issue of alternative cause for Robert M. Stark, M.D., Cardiology consultant for this case.

(footnote omitted).

Dr. Axelrod's expert report concluded:

> Jodilyn Druery received an influenza vaccination on October 26, 2016, at about 3:30PM. The influenza vaccination resulted in the expected elevation of inflammatory cytokines, including IL-6, with coronary artery vasospasm that resulted in her permanent heart damage at 11:00PM on October 27, 2016 (about 31-32 hours following the vaccination). She developed symptoms that resulted from spasm of her coronary arteries, leading to myocardial infarction, dysrhythmia and cardiac arrest. She was left with permanent heart damage, without evidence of a significant anatomic obstruction of her coronary arteries. As most individuals, who receive the influenza vaccine, do not suffer myocardial infarction, as with other individuals who develop problems following vaccination, Jodilyn Druery must have an increased sensitivity to the cytokines at the time of her vaccination on October 26, 2016. Therefore, given the medical records provided and peer reviewed literature, we have provided a theory of causation, linking the influenza vaccination received by Jodilyn Druery with her permanent heart damage.

Respondent filed several expert reports by cardiologist Shane LaRue, M.D., and immunologist Noel Rose, M.D., Ph.D. Dr. LaRue's expert report determined:

> Ms. Druery's presentation is best described by the term **Myocardial infarction with no obstructive coronary atherosclerosis (MINOCA),** which is defined as **"a syndrome with different causes, characterized by clinical evidence of MI with normal or near normalcoronary arteries on angiography (stenosis severity <50%)."** This syndrome encompasses several different underlying etiologies, namely: coronary artery vasospasm, eccentric coronary plaque, takotsubo syndrome, microvascular spasm, PVB 19 myocarditis, and coronary embolism.

> Of these potential etiologies, myocarditis and myopericarditis are rendered rather unlikely by her cardiac MRI, as it demonstrated a transmural infarct in the LAD [left anterior descending] territory with mural thrombus, rather than the diffuse inflammation seen with myocarditis. Coronary embolism is also of very low likelihood, as in that case one would expect abnormal coronary arteries on coronary angiography, with either an abrupt vessel stump or thrombotic material inside an epicardial coronary artery. Epicardial and microvascular coronary spasm are possible causes, but less likely based on her history. Specifically, coronary angiography noted no coronary spasm. Even without provocative testing (acetylcholine), coronary angiography alone can often precipitate coronary spasm in those at risk. She also had no prior episodes of angina, which is frequently observed in those with coronary spasm. Further, she had transmural infarct (severe damage requiring prolonged lack of blood flow) which is unlikely to result from coronary spasm. The remaining causes of MINOCA *(*no obstructive coronary atherosclerosis with positive remodeling/eccentric plaque and takotsubo syndrome*)* are both potential explanations for Ms. Druery's presentation as she has some features consistent with each.

(emphasis in original; internal reference and footnotes omitted; alteration added). Additionally, Dr. LaRue's expert report determined:

> **Takotsubo cardiomyopathy** is a *"reversible cardiomyopathy that is frequently precipitated by* a *stressful event and has* a *clinical presentation that is indistinguishable from* a *myocardial infarction* (chest pain and ST segment elevation on ECG [electrocardiogram]). It occurs predominantly in postmenopausal women, with approximately 90% of all cases presenting in women overall. Coronary angiography yields normal coronaries or mild atherosclerosis. Finally, cardiac imaging frequently demonstrates hypokinesis or akinesis[19] of the mid and apical segments of the left ventricle, with normal or hyper-dynamic function of the base. Ms. Druery's presentation was suggestive of takotsubo cardiomyopathy in that she is female, had ST elevation with no significant coronary disease, had normal LV [left ventricle] function with apical hypokinesis to dyskenisis, and demonstrated possible involvement in multiple coronary territories (apex, anterior septum from the LAD and inferior septum from the RCA [right coronary artery]) on her nuclear imaging. Additionally, takotsubo cardiomyopathy has been associated with migraine headaches as well as with the use of nortriptyline and zolmitriptan, a migraine treatment medication of the same class (a serotonin 5-HT1B, 10 receptor agonist) as Ms. Druery's sumatriptan. Takotsubo syndrome is less likely in Ms. Druery as her cardiac MRI demonstrated a transmural infarct localized to just the LAD territory and her substantial troponin elevation is higher than that generally seen in takotsubo. The other likely explanation for Ms. Druery's

[19] Akinesis is defined as "loss or impairment of voluntary activity (as of a muscle)." https://www.merriam-webster.com/dictionary/akinesis (last visited Feb. 29, 2024).

> presentation is myocardial infarction related to **no obstructive coronary atherosclerosis with positive remodeling (eccentric plaque disruption).** This clinical entity can present with chest pain, ST segment elevation on ECG, elevated troponin values, and no obstructive disease visible on coronary angiography. Additionally, patients with MI [myocardial infarction] related to no obstructive coronary atherosclerosis can demonstrate ischemia and infarction on cardiac MRI, as was the case for Ms. Druery. Considering her presentation, cardiac MRI with infarct in a single vessel (LAD) territory, and the degree of troponin elevation, Ms. Druery's MINOCA [myocardial infarction with nonobstructive coronary arteries] most likely represented **myocardial infarction related to no obstructive coronary atherosclerosis with positive remodeling (plaque disruption),** though **takotsubo cardiomyopathy** remains a reasonable possibility. Ms. Druery's VF [ventricular fibrillation] arrest was a result of her MINOCA.

(emphasis in original; internal reference and footnotes omitted; alterations and footnote added). Dr. LaRue concluded that "[t]here is currently no scientific evidence of any relationship between influenza vaccine and myocardial infarction or ventricular arrhythmia." (alteration added).

Another of respondent's experts, Dr. Rose, addressed the medical literature cited by petitioner's expert Dr. Stark. In his expert report, Dr. Rose stated:

> Doctor Stark concludes that an acute myocardial infarction was caused by coronary endothelial dysfunction due to an acute inflammatory reaction to the influenza vaccine. He provides four articles from the medical literature supporting this view. Carty et al, (2006) reported that, after influenza vaccination, acute phase responses were more elevated in men with severe carotid artery disease than in men with less severe disease. Responses were not uniform; of the parameters tested only the serum amyloid-a differed consistently between the patients and controls. C reactive protein and IL-6 are more widely used as measures of inflammation. The results do not indicate that inflammatory cytokines cause or promote cardiovascular disease. Fountoulaki and colleagues (2018), among others, reported that vaccination benefits patients with cardiovascular disease rather than adding to the injury. The Carty studies carried out at 24 hours reflects only the acute phase responses in the immediate post vaccination period. To show persistence of the inflammatory response, Doctor Spark cited an article (Glaser et al, 2003) which looked at IL-6 two weeks after vaccination. In this trial they compared patients with more severe symptoms of depression with milder degrees. Although IL-6 levels were slightly higher in the more depressed patients at baseline, the difference between fewer symptoms and more symptoms was significant two weeks after vaccination. The cytokine levels remained elevated when depression was constant, suggesting that the prolonged, enhanced inflammatory responses were due to the chronic depression rather than the influenza vaccine. Similarly, Liuba

> (2007) reviewed the literature on inflammatory markers and acute cardiovascular events and found that effects of mild inflammation persisted two weeks after vaccination. None of the studies show that the vaccine causes rapid inflammation in the heart.
>
> Rettir et al, (2003) reported a single case of vasculitis and myocardial infarction following influenza vaccination of a 32-year-old patient. While the single case studies are often useful in calling attention of the medical community to a possible association, more extensive studies have failed to show a significant connection between influenza vaccination and cardiovascular diseases (Smeeth et al., 2004; McNeil et al., 2018). The studies of small numbers of cases often represent chance co-occurrence and do not by themselves support a statistically valid association.
>
> In brief, these citations from the literature don't add credibility to Doctor Starks' hypothesis.

Dr. Rose's expert report concluded:

> Population-based studies show no valid association between Jodilyn Druery's vaccination on October 26, 2016, and her sudden, life-threatening heart attack on October 27. Mechanistic investigations reveal no plausible biologic connection between her local reaction to the vaccine and her sudden heart failure. There is no scientific basis for the claim that cardiovascular disease is caused or enhanced by today's non-living, purified influenza vaccine. It is highly unlikely than that the Fluzone given to Mrs. Drurey [sic] caused or contributed significantly to her cardiac disease.

(alteration added).

> Special Master Horner's decision determined:
>
> Dr. Rose's written opinion stresses that epidemiology has not only failed to detect any association between the flu vaccine and heart disease, but studies have also found that vaccination can actually diminish the severity of heart disease and it is now common clinical practice to recommend the flu vaccine for cardiac patients at risk of enhanced disease. Dr. Rose stresses that the flu vaccine, in particular, does not utilize an adjuvant to boost the immune response to vaccination. According to Dr. Rose, petitioner's post-vaccination symptoms are attributable to a local inflammatory response rather than a systemic inflammatory response, with no systemic inflammation being evident.

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *14 (internal references and footnotes omitted).

During the pendency of petitioner's case Dr. Rose passed away. Thereafter, respondent filed a report by another immunologist, Arnold Levinson, M.D. Dr. Levinson's expert report determined:

> Whereas signs of inflammation such as local injection swelling and pain, low-grade fever, headache and myalgias, variously seen post-seasonal flu vaccine administration of healthy subjects, is consistent with the action of the observed post-inflammatory cytokines, there is absolutely no evidence that these levels of cytokines induce any kind of acute cardio-vascular inflammatory events in healthy subjects studied. Moreover, and very importantly as Dr. Axelrod, himself, discussed in his response to Dr. Rose's report, robust epidemiological studies have shown that vaccination of patients who actually suffer from cardiovascular diseases like atherosclerosis and congestive heart failure (including those with history of MI) with seasonal influenza vaccine does not lead to the development of acute adverse cardiovascular events. Indeed, the published studies show that seasonal flu vaccination appears to have a beneficial effect on the underlying cardiovascular disease or no effect [sic] Accordingly, I think it is fair to say, that the medical literature, particularly, the epidemiological literature, does not support the opinion that seasonal influenza vaccine induced the petitioner's myocardial infarction.

(internal reference omitted; alteration added). As explained by Special Master Horner, "Dr. Levinson notes, as did Dr. Rose, that epidemiology suggests that the flu vaccine has either a beneficial effect on cardiovascular disease or no effect at all." Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *15.

Dr. Levinson's expert report concluded:

> In the final analysis, I believe it is highly unlikely that the seasonal influenza vaccine induced a systemic inflammatory response that led to Ms. Druery's myocardial infarction. She manifested mild post-vaccination symptoms frequently seen in the hours following influenza vaccination. Of note, her temperature at the time of her admission on October 27, 2016 was only 99^{o} F and she did not register a higher temperature on subsequent days in hospital. Furthermore, there was not a single laboratory test in the medical records associated with her hospital admissions and stays beginning on October 27[, 2016] that indicated she suffered from contemporaneous systemic inflammation. Furthermore, as Drs. Larue [sic] and Rose posited, the preponderance of population-based studies do not support the proposition that seasonal influenza vaccine induced the petitioner's myocardial infarction. Given my comments above, I believe to a high degree of medical certainty that the Fluzone vaccine Ms. Druery received on October 26, 2016 played no causal role in the development of acute MI [myocardial infarction] on October 27, 2016.

(alterations added).

On July 11, 2023, Special Master Horner issued his decision dismissing petitioner's case. See Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *22. Special Master Horner explained that to receive compensation for an off-Table injury, a petitioner must show that they have met the three prong requirements outlined in Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005), according to which petitioner must show: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278. Special Master Horner found that petitioner had not met her burden of proof under the Althen prongs. Special Master Horner began his analysis of the first Althen prong by noting:

> There is no meaningful debate in this case that infection is associated with adverse cardiac events, probably including an inflammatory component. There is also no significant debate that the flu vaccine produces temporary elevations in inflammatory cytokines. Significantly, however, both parties' experts have come forward with literature demonstrating that the flu vaccine has a cardioprotective effect.

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *16 (internal references and footnotes omitted). Special Master Horner continued:

> The reasons for this cardioprotective effect are not entirely clear, but may have to do simply with the ability of the flu vaccine to prevent infections, which are themselves associated with cardiovascular events. This likely leads to a statistical reduction in cardiovascular events. That does not in itself mean the flu vaccine is incapable of causing acute cardiac events such as myocardial infarction. However, it does mean that the inflammatory response to vaccination cannot be merely equated in its cardiovascular effects with infection.

Id. (internal reference omitted). Special Master Horner determined, therefore, "without treating epidemiology as dispositive, petitioner's stressing of the various studies of record that merely demonstrate the flu vaccine to elevate cytokines to some degree, but without demonstration of any relevant adverse events, will not be persuasive without more." Id. at *17.

Turning to the specific studies cited by petitioner's experts, Special Master Horner reasoned:

> The four articles cited by Dr. Stark are inadequate to support his contention that the flu vaccine can cause myocardial infarction. Carty et al. examined inflammatory markers in 43 men with severe carotid artery disease and 61 men without. (Carty, et al.) They found "mild, but measurable" acute phase responses among both groups. Markers for CRP [c-reactive protein], IL-6, and serum amyloid-a (SSA) were higher in those with disease, but only significantly so for SSA. The authors did not report on adverse events and

> concluded only that acute phase response variability may be predictive of underlying vascular disease. Liuba et al. found that endothelial abnormalities in human vasculature can persist for up to two weeks following a flu vaccination; however, given the size of the study and limited follow up, the authors disclaimed any insight into the significance of this finding, noting instead that prior studies have shown the flu vaccine to be cardioprotective. (Liuba, et al.) Glaser et al. found that patients with depressive symptoms may experience a stronger inflammatory response to vaccination with no indication the difference would affect cardiovascular health. (Glaser, et al.) Ritter et al. is a single case report of a woman who experienced vasculitis and myocardial infarction following a flu vaccine. (Ritter, et al.) However, Dr. LaRue stresses that the subject's vasculitis distinguishes the case report from this case.
>
> Dr. Axelrod cites some of the same literature as Dr. Stark (most notably Liuba, et al.), but also more specifically seeks to bridge the remaining gap between vaccine cytokine response and cardiovascular injury by discussing vasospasms. Dr. LaRue agrees that coronary artery vasospasm is a potential cause of MINOCA. However, the purported link to vaccination remains unpersuasive.

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *17-18 (internal references and footnote omitted; alteration added). Special Master Horner explained:

> Dr. Axelrod relies in significant part on literature measuring cytokine levels relative to vasospasm in the context of subarachnoid hemorrhage, most notably a study by Rasmussen, et al. However, Dr. Levinson questions whether this is a relevant context for assessing coronary artery spasm. Dr. Levinson's concern is especially well taken when comparing the Rasmussen study against the Fassbender study, a separate study cited by Dr. Axelrod regarding subarachnoid hemorrhage. (Fassbender, et al.) The Fassbender study examined several cytokines, including IL-6 and TNF-α, using cerebral spinal fluid. These cytokines were elevated among subarachnoid hemorrhage patients when measured this way and were correlated with cerebral vascular complications. The authors explained that in the context of subarachnoid hemorrhage, the excessive inflammatory response originates in and is "compartmentalized" to the spine and subarachnoid space, specifically affecting the cerebral vasculature.

Id. at *18 (internal references omitted).

Special Master Horner further examined the studies cited by Dr. Axelrod and determined:

> Dr. Axelrod stresses the Rasmussen study because it shows elevated cytokines associated with subarachnoid hemorrhage that are ultimately lower than what was observed post-vaccination in an unrelated study by

> Kashiwagi, et al. (citing Kashiwagi, et al.) Dr. Axelrod's comparison of the cytokine levels measured in Rasmussen to the post-vaccination cytokine levels observed in Kashiwagi is unpersuasive given that none of the cytokines measured in Kashiwagi were associated with vasospasm in the Rasmussen study. Dr. Axelrod's theory ultimately relates to vasospasm, not subarachnoid hemorrhage, and Dr. Axelrod has not substantiated that subarachnoid hemorrhage is of any relevance in itself.

Id. (internal reference omitted). Special Master Horner also addressed a different study relied on by Dr. Axelrod.

> Dr. Axelrod additionally cites the Bowman study, in which vasospasm of the femoral artery was induced by IL-6 in rats and the Gardiner study, in which TNF-α and IL-1β were used to invoke cardiovascular response in rats; however, these studies are not persuasive given Dr. Axelrod's specific reliance on Rasmussen, et al. Regardless of what the rat models showed, Rasmussen found no association between either IL-6 or TNF-α and vasospasm in humans. (Rasumussen [sic], et al.) Even setting the Rasmussen study aside, it is still not clear that these rat studies are reasonably similar to what petitioner's experts theorize happened in this case. Of note, the Bowman authors explain, consistent with the above, that their model is intended to mimic cerebral vasospasm and that human studies have reached inconsistent results with respect to whether cytokines contribute to subarachnoid hemorrhage. (Bowman, et al.)

Id. at *19 (emphasis in original; alteration added; internal references omitted).

Reviewing the record before him, including the expert reports submitted by both parties and the medical literature, Special Master Horner, concluded, regarding Althen prong 1, "[c]onsidering all of this collectively and in the context of the record as a whole, I conclude that petitioner has not preponderantly established that the flu vaccine can cause acute cardiac events, including myocardial infarction." Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *19 (alteration added).

Regarding Althen prong 2, which required petitioner to show "a logical sequence of cause and effect showing that the vaccination was the reason for the injury," Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278, Special Master Horner noted that

> Petitioner stresses in her brief that she did not have a history of heart disease or heart attack, quoting Dr. Stark's assessment that she was a woman "in excellent health, with a history of occasional migraine headaches" as well as Dr. Glickman's October 26, 2016, assessment of "no cardiac pulmonary GI or GU symptoms Petitioner implies that, but for her proposed explanation of events, her condition would otherwise be mysterious or unlikely. Importantly, however, petitioner did have several risk factors for an acute cardiovascular event.

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *19. Special Master Horner explained

> Both Dr. Morgan for petitioner and Dr. LaRue for respondent agree that petitioner's atherosclerosis of the small diagonal artery is significant to assessing her condition even though it is not directly implicated in her myocardial infarction. Specifically, they both opine that the fact of this finding makes it more likely that petitioner's myocardial infarction could have been caused by an undetected clot or plaque. Additionally, petitioner also had a documented history of hypertension, which is a risk factor for atherosclerosis. Further to this, petitioner's immunology expert, Dr. Axelrod, has filed review articles indicating that migraine disorders are considered an overall risk factor for cardiovascular disease. While petitioner asserts this supports her claim because migraine disorders show a predisposition to vasospasm, the literature cited by Dr. Axelrod confirms the reason for the association between migraines and cardiovascular events is unknown. Thus, the evidence regarding migraines is sufficient only to establish that petitioner was statistically at risk for cardiovascular disease as a general matter, i.e., this was a risk factor regardless of what petitioner theorizes.

Id. (internal references omitted).

The Special Master's decision further noted that "Petitioner also stresses the symptoms she experienced soon after vaccination, including swelling, hives, headache, arm pain, and malaise." Id. Special Master Horner addressed petitioner's symptoms by determining:

> The fact of these symptoms is not reasonably contested. However, because Drs. Stark and Axelrod were not persuasive in establishing that post-vaccination inflammation is clinically meaningful to myocardial infarction, the fact that petitioner suffered constitutional symptoms following her vaccination is of diminished significance. Respondent's experts persuasively opined that, although technically systemic as petitioner contends, these symptoms are representative only of mild inflammation. As Dr. Levinson stressed, these symptoms commonly occur in healthy vaccinees and they are not established as a precursor to adverse cardiac events.

Id. at *20 (internal reference omitted). Special Master Horner's analysis continued:

> In addition to petitioner's post-vaccination symptoms, Dr. Stark cites two other factors as indicating petitioner's acute cardiac event was likely due to systemic inflammation. First, Dr. Stark stresses that multiple areas of the heart were affected. He contends that this makes it far more likely petitioner's acute event resulted from a systemic cause. There is a difference of clinical judgment between the parties' experts on whether Dr. Stark is correct to implicate two areas of damage. But regardless of whether petitioner's experts are more persuasive on that point, both Dr. LaRue and Dr. Morgan agree that while the two areas at issue may be supplied by two

> separate arteries, they can also be supplied by the same artery. Although there is no definitive indication of which category petitioner falls into, this undercuts Dr. Stark's suggestion that damage to these two areas must necessarily be from a systemic source. Second, Dr. Stark stresses petitioner's WBC [white blood count] count as evidence petitioner was undergoing an inflammatory response. However, petitioner's immunology expert, Dr. Axelrod, and respondent's immunology expert, Dr. Levison, both opine that petitioner's WBC count was due to her treatment with glucocorticoid agents as observed by Dr. Orlovic. Respondent's cardiology expert, Dr. LaRue, also suggests that elevated WBC would in any event be consistent with myocardial infarction itself. Even to the extent Dr. Stark stresses the preponderance of neutrophils, Dr. LaRue explains that this too is consistent with myocardial infarction.

Id. (emphasis in original; internal reference omitted; alteration added). Special Master Horner also addressed Dr. Stark's opinion that "Dr. LaRue's alternative explanation reflects an unlikely series of events," writing

> However, Dr. LaRue indicates that Dr. Stark misinterpreted his opinion. Specifically, Dr. Stark questioned why Dr. LaRue would opine that positive remodeling could happen within hours, but Dr. LaRue explained that his view is that the plaque buildup and positive remodeling occurred over time prior to vaccination. Dr. Stark also questioned why, even if the plaque ultimately dissolved at the time of the acute event, there was not residual evidence of the plaque. Dr. LaRue offered a competing clinical judgment that this process can result in no remaining significant lesion. He also suggests that some residual damage could be picked up by ultrasound rather than angiography. Dr. Stark did not otherwise challenge Dr. LaRue's explanation of MINOCA [myocardial infarction with nonobstructive coronary arteries] more broadly, or his specific assertion that eccentric plaques are among the established causes of MINOCA. Petitioner's other cardiology expert, Dr. Morgan, likewise opines that it is possible for a blockage causing myocardial infarction to ultimately evade the cardiac catheterization imaging. As noted above, both Dr. LaRue and Dr. Morgan find significance in the fact that petitioner did have atherosclerosis of some degree, albeit in a location that was not implicated in her myocardial infarction.

Id. (internal reference omitted; alteration added).

In his decision Special Master Horner stated: "I have considered the views of petitioner's treating physicians, but do not find that any of the treating physician statements meaningfully support vaccine causation." Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *21. Special Master Horner explained:

> Petitioner stresses that her physicians did not reach any alternative conclusion regarding the cause of her cardiac event and, in fact, opined that it was vaccine-caused. In particular, petitioner quotes the following by Dr.

> Miller, petitioner's treating cardiologist: "[i]it is very likely that her cardiac event in 2016 was Takotsubo syndrome, however her wall motion appears to have not recovered. The precipitating event is unclear, however appears to be related to the influenza vaccine."
>
> Dr. Miller's statement is not consistent with petitioner's claim given that it is premised on his acceptance that petitioner's history very likely constituted Takotsubo syndrome. Her experts, by contrast, did not support such a view. Neither Dr. Stark nor Dr. Axelrod discussed Takotsubo syndrome as any part of their causal opinion. Dr. Morgan did indicate that Takotsubo syndrome can result from systemic inflammation, but this was not substantiated. Moreover, Dr. LaRue indicates that his review of the medical literature refutes that assertion. In any event, Dr. Morgan opined that petitioner did not suffer Takotsubo syndrome. Without additional expert support, Dr. Miller's statement is inadequate standing alone to substantiate that the flu vaccine could reasonably be considered a precipitant of Takotsubo syndrome.
>
> Moreover, considering the quotation from Dr. Miller as a whole, it is best interpreted as raising only a suspicion of vaccine causation. That is, prefaced with the caveat that the precipitating event is "unclear," use of the word "appears" falls short of stating a conclusion. Indeed, petitioner acknowledges that "[t]his statement from a treating physician is basically indicating that we may never know for sure what happened to [petitioner]" but argues that it is an assertion that "based on the clinical presentation, the timing after immunization, and the lack of other precipitating events, it was probably the shot."

Id. (internal references and footnote omitted; alterations in original).

Additionally, the Special Master considered the other treating physician statements contained in petitioner's medical records. Special Master Horner wrote:

> In 2018, petitioner received a vaccine exemption from a physician's assistant in Dr. Lewis's office; however, the statement indicates only vaguely that her vaccine reaction "affected her heart." This is especially unpersuasive given the cardiologist's explicit conclusion that the precipitating event is unclear. Other statements within the medical records document the fact of petitioner having experienced a post-vaccination reaction without linking that reaction to petitioner's cardiac condition. For example, her November 1, 2016, discharge includes "[status post] flu shot reaction" without any indication it was causally related to any of the other listed diagnoses. Dr. Orlovic and Dr. Mateo-Bilbeau both recorded the history of vaccine reaction without assessing it as causally related. Several other records are limited to merely recording petitioner's own assertion that her cardiac event was due to her flu vaccination.

Id. (internal reference and footnotes omitted; alteration in original). Special Master Horner concluded: "For all these reasons, I find that petitioner has not met her burden under Althen prong two of preponderantly establishing a logical sequence of cause and effect demonstrating that her flu vaccine did cause her injury." Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *22.

Regarding the third Althen prong, which requires "a showing of a proximate temporal relationship between vaccination and injury," Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278, Special Master Horner concluded:

> In this case, petitioner's experts opine that petitioner's cardiac event was caused by post-vaccination systemic inflammation. They assert that the event, occurring about 31 hours post-vaccination, happened during a timeframe in which it is medically reasonable to conclude that post-vaccination inflammation would be persisting. Rather than refuting this specific contention with respect to timing, respondent's experts primarily contest that the type of inflammation petitioner experienced could cause a cardiac event at all. Thus, for all the reasons discussed in the preceding sections, this case turns on Althen prongs one and two. Because Althen prong three coincides with Althen prong one, petitioner's inability to meet her burden under prong one effectively precludes her from being able to meet her burden under Althen prong three. Even assuming that petitioner satisfied Althen prong three, that alone would not satisfy petitioner's overall burden of proof. Veryzer v. Sec'y of Health & Human Servs., 100 Fed. Cl. 344, 356 (2011) (explaining that a "temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury."); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1364-65 (Fed. Cir. 2012) (holding the special master did not err in resolving the case pursuant to Prong Two when respondent conceded that petitioner met Prong Three).

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *22 (emphasis in original).

Therefore, Special Master Horner concluded:

> There is no question that petitioner has suffered and that the events discussed throughout this decision profoundly affected her life. She has my sympathy and I do not question her sincerity in bringing this claim. However, for all the reasons discussed above, I find that petitioner has not met her burden of proof in this case.

Id.

After Special Master Horner issued his decision, petitioner timely filed a Motion for Review of Special Master Horner's decision. Petitioner argues "[t]he Special Master improperly elevates Petitioner's burden under Althen Prong 1 in various ways." (alteration added). Petitioner argues:

> The Special Master fundamentally misunderstands (or specifically modifies) Petitioner's theory. Petitioner's expert, Dr. Stark, presents a sound and reliable theory of a ". . . systemic trigger causing transient spasm or inflammation of one or more coronary arteries." (emphasis in original). Petitioner is not merely stating that if infection can cause an adverse effect, so can vaccination. She presented medical literature supporting Dr. Stark's assertion that "[i]t has been demonstrated that influenza vaccine causes an acute phase inflammatory response within 24 hours after immunization."

(alteration and omission in original; internal references omitted). Petitioner also argues that "[c]ontrary to the Special Master's contentions, the medical literature provides more than adequate support and cannot be ignored." (alteration added). Regarding Althen prong 1, petitioner concludes: "To state that Petitioner did not meet her burden of proof with this level of treating physician and expert support is arbitrary and capricious, and contrary to law in terms of the burden of proof applicable to Petitioners in the Vaccine Program."

Separately, petitioner argues to this court that "[t]he Special Master's minimization of the opinions of Mrs. Druery's treaters is arbitrary and capricious as he erroneously elevates the burden of proof Mrs. Druery's must satisfy under Althen Prong 2." (alteration added). Petitioner underlines her argument by alleging:

> **Treating physicians clearly expressed their opinion that Mrs. Druery's injury is vaccine related**. Yet the Special Master states, "I have considered the views of petitioner's treating physicians, but do not find that any of the treating physician statements meaningfully support vaccine causation." This is contrary to law, and simply a [sic] unsupportable conclusion. The Special Master has placed an impossible burden upon Mrs. Druery, and it is unclear what language from a treating physician would satisfy the Special Master's erroneously elevated standards.

(emphasis in original; internal reference omitted; alteration added). Petitioner argues "Mrs. Druery has one treating physician stating '**appears to be related to the influenza vaccine,**' coupled with another treating physician granting a vaccine exemption. Together, this is incredibly probative evidence exceeding Petitioner's burden," but contends Special Master Horner's decision requires "her treating physicians to state causation to medical certainty." (emphasis in original).

In response, respondent argues

> the Special Master applied the correct burden of proof and articulated findings that were neither arbitrary nor capricious. His conclusion that petitioner is not entitled to compensation was based on a thorough review of the evidence and is supported by both plausible inferences and a rational basis. Petitioner's disagreement with the Special Master's conclusions does not justify disturbing his well-supported Decision.

Regarding Althen prong 1, respondent argues that "[t]he Special Master held petitioner to the proper burden of proof and reasonably concluded she failed to satisfy

Althen prong one because she failed to present a reliable theory that the flu vaccine can cause MI." (alteration added). Further, respondent argues that "[t]he Special Master properly concluded that petitioner did not preponderantly establish that the flu vaccine can cause acute cardiac events, including MI. Petitioner provided no evidence specifically demonstrating that flu vaccine can cause acute cardiac events." (alteration added; internal reference omitted).

Regarding Althen prong 2, respondent posits that "[t]he Special Master properly found that the statements of petitioner's treating physicians were insufficient to establish that the flu vaccine did cause petitioner's MI," (alteration added), and argues

> Petitioner inexplicably argues that "multiple" treating physicians "clearly" opined that her cardiac event was vaccine caused. Not only do the records themselves reveal otherwise, but it is apparent from the Special Master's decision that he carefully considered the relevant medical records and statements, drew plausible inferences from them, and articulated a rational basis for his conclusion that none of the statements of the treating physicians "meaningfully support vaccine causation."

(internal reference omitted). Respondent also claims that "[t]he Special Master properly concluded that petitioner's medical records did not otherwise establish that the flu vaccination caused her MI," (alteration added), and contends

> Petitioner's causation theory was predicated on systemic inflammation, yet, notably, there was no testing of inflammatory markers in the record. The Special Master found the opinions of respondent's experts more persuasive, specifically that there was insufficient evidence that petitioner experienced a systemic inflammation that caused her MI, or that she had anything more than "mild inflammation" soon after vaccination.
>
> Respondent concludes:
>
> Fundamentally, petitioner simply disagrees with the Special Master's factual findings and weighing of the evidence, which is not a proper ground for reversal. Petitioner has failed to demonstrate that the Special Master erred, or that his actions were in any way arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. Therefore, his Decision is entitled to deference and should be affirmed.

After the Motion for Review was fully briefed the court held oral argument.

D I S C U S S I O N

When reviewing a Special Master's decision, the assigned Judge of the United States Court of Federal Claims shall:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in

> accordance with law and issue its own findings of fact and conclusions of law, or
> (C) remand the petition [filed under § 300aa-11] to the special master for further action in accordance with the court's direction.

Munn v. Sec'y of Health & Hum. Servs., 970 F.2d 863, 867 (Fed. Cir. 1992) (alteration in original); see also 42 U.S.C. § 300aa-12(e)(2) (2018); Larson v. Sec'y of Health & Hum. Servs., 168 Fed. Cl. 24, 27 (2023). The legislative history of the Vaccine Act states: "The conferees have provided for a limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently, but rather in those cases in which a truly arbitrary decision has been made." H.R. Conf. Rep. No. 101-386, at 516–17, reprinted in 1989 U.S.C.C.A.N. 3018, 3120 (alteration added).

In Markovich v. Secretary of Health & Human Services, the United States Court of Appeals for the Federal Circuit wrote, "[u]nder the Vaccine Act, the Court of Federal Claims reviews the Chief Special Master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.' 42 U.S.C. § 300aa-12(e)(2)(B)." Markovich v. Sec'y of Health & Hum. Servs., 477 F.3d 1353, 1355–56 (Fed. Cir.), cert. denied, 552 U.S. 816 (2007); see also Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1381 (Fed. Cir. 2021); Sharpe v. Sec'y of Health & Hum. Servs., 964 F.3d 1072, 1077 (Fed. Cir. 2020) ("This court thus performs the same task as the Court of Federal Claims and reviews the special master's legal determinations *de novo*, fact findings under an arbitrary and capricious standard, and discretionary rulings for an abuse of discretion." (citing Munn v. Sec'y of Health & Hum. Servs., 970 F.2d at 870-73, 870 n.10)); see also K.G. v. Sec'y of Health & Hum. Servs., 951 F.3d 1374, 1379 (Fed. Cir. 2020); Oliver v. Sec'y of Health & Hum. Servs., 900 F.3d 1357, 1360 (Fed. Cir. 2018) (citing Milik v. Sec'y of Health & Hum. Servs., 822 F.3d 1367, 1375–76 (Fed. Cir. 2016)); Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs., 717 F.3d 1363, 1366 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2013) (The United States Court of Appeals for the Federal Circuit stated that "we 'perform[ ] the same task as the Court of Federal Claims and determine[ ] anew whether the special master's findings were arbitrary or capricious.'" (alterations in original) (quoting Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000))); W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1355 (Fed. Cir. 2013); Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1363 (Fed. Cir. 2012); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1350 (Fed. Cir. 2008); Avera v. Sec'y of Health & Hum. Servs., 515 F.3d 1343, 1347 (Fed. Cir.) ("Under the Vaccine Act, we review a decision of the special master under the same standard as the Court of Federal Claims and determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" (quoting 42 U.S.C. § 300aa-12(e)(2)(B))), reh'g and reh'g en banc denied (Fed. Cir. 2008); Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1277; Hodge v. Sec'y of Health & Hum. Servs., 168 Fed. Cl. 117, 123 (2023); Bello v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 517, 522 (2023); Simeone v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 389, 393 (2023); Faup v. Sec'y of Health & Hum. Servs., 147 Fed. Cl. 445, 458 (2019). The abuse of discretion standard is applicable when the special master excludes evidence or limits the record upon which

he or she relies. See Munn v. Sec'y of Health & Hum. Servs., 970 F.2d at 870. The United States Court of Appeals for the Federal Circuit has indicated that:

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard; and discretionary rulings under the abuse of discretion standard. The latter will rarely come into play except where the special master excludes evidence.

Id. at 871 n.10; see also Winkler v. Sec'y of Health & Hum. Servs., 88 F.4th 958, 963 (Fed. Cir. 2023); Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d at 1381 ("We do not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder" (citing Porter v. Sec'y of Health & Hum. Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011))); Carson ex rel. Carson v. Sec'y of Health & Hum. Servs., 727 F.3d 1365, 1369 (Fed. Cir. 2013); Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs., 717 F.3d at 1366; W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d at 1355; Griglock v. Sec'y of Health & Hum. Servs., 687 F.3d 1371, 1374 (Fed. Cir. 2012); Porter v. Sec'y of Health & Hum. Servs., 663 F.3d at 1249 (explaining that the reviewing court "do[es] not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." (citing Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010)), reh'g and reh'g en banc denied (Fed. Cir. 2012); Dodd v. Sec'y of Health & Hum. Servs., 114 Fed. Cl. at 56. "[T]he special masters have broad discretion to weigh evidence and make factual determinations." Dougherty v. Sec'y of Health & Hum. Servs., 141 Fed. Cl. 223, 229 (2018); see also Simeone v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. at 393 ("When reviewing a special master's decision, this Court cannot 'substitute its judgment for that of the special master merely because it might have reached a different conclusion.'" (quoting Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 718 (2009))). As explained by the Federal Circuit:

> With regard to both fact-findings and fact-based conclusions, the key decision maker in the first instance is the special master. The Claims Court owes these findings and conclusions by the special master great deference—no change may be made absent first a determination that the special master was "arbitrary and capricious."

Munn v. Sec'y of Health & Hum. Servs., 970 F.2d at 870; see also 42 U.S.C. § 300aa-12(e)(2)(B).

"'[R]eversible error is extremely difficult to demonstrate if the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.'" Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d at 1381 (quoting Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d at 1360); see also Winkler v.

Sec'y of Health & Hum. Servs., 88 F.4th at 963; Milik v. Sec'y of Health & Hum. Servs., 822 F.3d at 1376; Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d at 1363 ("[I]f the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.'" (quoting Hines v. Sec'y of Health & Hum. Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991))); Porter v. Sec'y of Health & Hum. Servs., 663 F.3d at 1253–54; Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d at 1360; Simeone v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. at 393; Dixon v. Sec'y of Health & Hum. Servs., 61 Fed. Cl. 1, 8 (2004) ("The court's inquiry in this regard must therefore focus on whether the Special Master examined the 'relevant data' and articulated a 'satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" (quoting Motor Vehicle Mfrs. Association v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)))).

As noted by the United States Court of Appeals for the Federal Circuit:

> Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs., 717 F.3d at 1366–67 (alterations in original) (quoting Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)); Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d at 1363; Locane v. Sec'y of Health & Hum. Servs., 685 F.3d 1375, 1380 (Fed. Cir. 2012). The United States Court of Appeals for the Federal Circuit has explained the reviewing courts "'do not sit to reweigh the evidence. [If] the special master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious.'" Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs., 717 F.3d at 1367 (modification in original) (quoting Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d at 1363); see also K.G. v. Sec'y of Health & Hum. Servs., 951 F.3d at 1379 ("With respect to factual findings, however, we will uphold the special master's findings of fact unless they are clearly erroneous." (citing Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278)); Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d at 1363 (citing Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010)).

The United States Court of Appeals for the Federal Circuit has explained that:

> A petitioner can establish causation in one of two ways. Id. [Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d at 1341] If the petitioner shows that he or she received a vaccination listed on the Vaccine Injury Table, 42

> U.S.C. § 300aa–14, and suffered an injury listed on that table within a statutorily prescribed time period, then the Act presumes the vaccination caused the injury. Andreu [ex rel. Andreu] v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1374 (Fed. Cir. 2009). Where, as here, the injury is not on the Vaccine Injury Table, the petitioner may seek compensation by proving causation-in-fact.

Milik v. Sec'y of Health & Hum. Servs., 822 F.3d at 1379 (alterations added) see also W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d at 1356; Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d at 1346; Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1356 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2006), cert. denied, 551 U.S. 1102 (2007); Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144, 1147–48 (Fed. Cir. 1992); O.M.V. v. Sec'y of Health & Hum. Servs., 157 Fed. Cl. 376, 384 (2021); Faup v. Sec'y of Health & Hum. Servs., 147 Fed. Cl. at 458; Dodd v. Sec'y of Health & Hum. Servs., 114 Fed. Cl. at 50; Paluck v. Sec'y of Health & Hum. Servs., 104 Fed. Cl. 457, 467–68 (2012).

When proving eligibility for compensation for a petition under the Vaccine Act, a petitioner must establish by a preponderance of the evidence that he received a vaccine set forth in the Vaccine Injury Table and that injury caused by the vaccination occurred within the required amount of time. See Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278; see also 42 U.S.C. § 300aa-11(c)(1)(A). Regarding the preponderance of the evidence standard, the Vaccine Act requires "'the trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact's existence.'" Moberly ex rel. Moberly v. Sec'y of Health and Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (alterations in original) (quoting Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Trust for S. Cal., 508 U.S. 602 (1993)). In demonstrating this preponderance of evidence, petitioner may not rely on his or her testimony alone to establish preponderant evidence of vaccine administration. According to the Vaccine Act, "[t]he special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1).

In weighing the evidence, the Special Master has discretion to determine the relative weight of the evidence presented, including contemporaneous medical records and oral testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (finding that the Special Master had thoroughly considered evidence in record, had discretion not to hold an additional evidentiary hearing); see also Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d at 1368 (finding it was not arbitrary or capricious for the Special Master to weigh diagnoses of different treating physicians against one another, including when their opinions conflict).

> "Clearly it is not then the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder."

Dodd v. Sec'y of Health & Hum. Servs., 114 Fed. Cl. at 56 (quoting Munn v. Sec'y of Health & Hum. Servs., 970 F.2d at 870 n.10); see also Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d at 1349; Rich v. Sec'y of Health & Hum. Servs., 129 Fed. Cl. 642, 655 (2016); Paluck v. Sec'y of Health & Hum. Servs., 104 Fed. Cl. at 467 ("So long as those findings are 'based on evidence in the record that [is] not wholly implausible,' they will be accepted by the court." (quoting Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d at 1363 (alteration in original))). "Determinations subject to review for abuse of discretion must be sustained unless 'manifestly erroneous.'" Heddens v. Sec'y of Health & Hum. Servs., 143 Fed. Cl. 193 (2019) (quoting Piscopo v. Sec'y of Health & Hum. Servs., 66 Fed. Cl. 49, 53 (2005) (citations omitted)).

Additionally, a Special Master is "not required to discuss every piece of evidence or testimony in [his or] her decision." Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. at 728 (brackets added); see also Mosley v. Sec'y of Health & Hum. Servs., 119 Fed. Cl. 734, 743 (2015). As explained by a Judge of the United States Court of Federal Claims:

> "[W]hile the special master need not address every snippet of evidence adduced in the case, see id. [Doe v. Sec'y of Health & Hum. Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010)], he [or she] cannot dismiss so much contrary evidence that it appears that he 'simply failed to consider genuinely the evidentiary record before him [or her].'"

Paluck ex rel. Paluck v. Sec'y of Health & Hum. Servs., 104 Fed. Cl. at 467 (quoting Campbell v. Sec'y of Health & Hum. Servs., 97 Fed. Cl. 650, 668 (2011))) (alteration added). A Special Master is required to acknowledge that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body," even if the possible link between the vaccine and the injury is "hitherto unproven." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1280; see also Porter v. Sec'y of Health & Hum. Servs., 663 F.3d at 1261. In that vein, "close calls regarding causation are resolved in favor of injured claimants." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1280 (citing Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548–49 (Fed. Cir. 1994)).

Under the off-Table theory of recovery, a petitioner is entitled to compensation if he or she can demonstrate, by a preponderance of the evidence, that the recipient of the vaccine sustained, or had significantly aggravated, an illness, disability, injury, or condition not set forth in the Vaccine Injury Table, but which was caused by a vaccine that is listed on the Vaccine Injury Table. See 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii)(I), 300aa-13(a)(1)(A); see also LaLonde v. Sec'y of Health & Hum. Servs., 746 F.3d 1334, 1339 (Fed. Cir. 2014); W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d at 1356 ("Nonetheless, the petitioner must do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence." (quoting Moberly ex rel. Moberly v. Sec'y of Health &

Hum. Servs., 592 F.3d at 1322)); Hines v. Sec'y of Health & Hum. Servs., 940 F.2d at 1525; A.Y. by J.Y. v. Sec'y of Health & Hum. Servs., 152 Fed. Cl. 588, 595 (2021).

While scientific certainty is not required, the Special Master "is entitled to require some indicia of reliability to support the assertion of the expert witness." Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d at 1324; see also Hazlehurst v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 473, 479 (2009), aff'd, 604 F.3d 1343 (Fed. Cir. 2010) (quoting Andreu ex rel. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d at 1379).

To establish causation in fact for a Non-Table claim, such as petitioner's claim in the above captioned case, a petitioner must satisfy all three of the elements established by the United States Court of Appeals for the Federal Circuit in Althen v. Secretary of Health & Human Services, 418 F.3d at 1278. See Winkler v. Sec'y of Health & Hum. Servs., 88 F.4th at 961; Sanchez v. Sec'y of Health & Hum. Servs., 34 F.4th 1350, 1353 (Fed. Cir. 2022); Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs., 717 F.3d at 1367; Porter v. Sec'y of Health & Hum. Servs., 663 F.3d at 1249; Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d at 1322; Andreu ex rel. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d at 1374–75; Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d at 1355; Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006); C.K. v. Sec'y of Health & Hum. Servs., 113 Fed. Cl. 757, 766 (2013).

With regard to the first Althen prong, "a medical theory causally connecting the vaccination and the injury," the Federal Circuit in Althen analyzed the preponderance of evidence requirement as allowing medical opinion as proof, even without scientific studies in medical literature that provide "objective confirmation" of medical plausibility. See Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278, 1279–80; see also Shapiro v. Sec'y of Health & Hum. Servs., 105 Fed. Cl. 353, 358 (2012), aff'd, 503 F. App'x 952 (Fed. Cir. 2013). In rejecting a requirement that a claimant under the Vaccine Act prove confirmation of medical plausibility from the medical community and medical literature, the Federal Circuit in Althen v. Secretary of Health & Human Services, relied on Knudsen v. Secretary of Health & Human Services, 35 F.3d 543, 548–49 (Fed. Cir. 1994), in which the Federal Circuit wrote, "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1280. Rather, a petitioner must preponderantly establish that the vaccine at issue can cause the petitioner's injury by providing a "'reputable medical or scientific explanation' for its theory." Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting Moberly ex rel. Moberly v. Sec'y of Health and Hum. Servs., 592 F.3d at 1322). "While it does not require medical or scientific certainty, it must still be 'sound and reliable.'" Id. (quoting Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d at 548–49).

The second prong of the Althen test requires the petitioner to demonstrate "a logical sequence of cause and effect showing that the vaccination was the reason for the injury" by a preponderance of the evidence. Althen v. Sec'y of Health & Hum. Servs., 418

F.3d at 1278; see also Sanchez v. Sec'y of Health & Hum. Servs., 34 F.4th at 1353; Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d at 1355. In order to prevail, the petitioner must show "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); see also Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012). In Capizzano v. Secretary of Health & Human Services, 440 F.3d at 1326, the Federal Circuit stated, "'[a] logical sequence of cause and effect' means what it sounds like-the claimant's theory of cause and effect must be logical. Congress required that, to recover under the Vaccine Act, a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d at 1326 (quoting 42 U.S.C. §§ 300aa–11(c)(1)–13(a)(1) (2006)); see also Cozart v. Sec'y of Health & Hum. Servs., 126 Fed. Cl. 488, 498 (2016) (quoting Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278)

The third prong of the Althen test requires the petitioner to demonstrate, by a preponderance of evidence, that there is "a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278; see also Sanchez v. Sec'y of Health & Hum. Servs., 34 F.4th at 1353. The United States Court of Appeals for the Federal Circuit emphasized the importance of a temporal relationship in Pafford v. Secretary of Health and Human Services, when it noted that, "without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm." Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d at 1358. "Evidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis." Id. (citing Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d at 1326).

According to the Federal Circuit in Capizzano v. Secretary of Health & Human Services, evidence used to satisfy one of the Althen prongs may overlap with and be used to satisfy another prong. See Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d at 1326 ("We see no reason why evidence used to satisfy one of the Althen III [Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1274] prongs cannot overlap to satisfy another prong." (alteration added)). If a petitioner satisfies the Althen burden and meets all three prongs of the test, the petitioner prevails, "unless the government demonstrates that the injury was caused by factors unrelated to the vaccine." Sanchez v. Sec'y of Health & Hum. Servs., 34 F.4th at 1353 (alteration added) (citing 42 U.S.C. § 300aa-13(a)(1)(B)); see also Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d at 547 (brackets in original; quotation omitted).

Althen Prong 1

In the above captioned case, at the end of Special Master Horner's analysis of Althen prong 1, the Special Master concluded: "Considering all of this collectively and in the context of the record as a whole, I conclude that petitioner has not preponderantly

established that the flu vaccine can cause acute cardiac events, including myocardial infarction." Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *19. As noted above, petitioner in the Motion for Review argues "[t]he Special Master has arbitrarily and capriciously elevated Petitioner's burden of proof under Althen Prong 1." (alteration added).

To address the Special Master's determination under Althen prong 1 in the Motion for Review, petitioner argues "[s]he presented medical literature supporting Dr. Stark's assertion that '[i]t has been demonstrated that influenza vaccine causes an acute phase inflammatory response within 24 hours after immunization.' In susceptible individuals, this response causes deleterious cardiac effects." (internal reference omitted; first alteration added). Specifically, petitioner criticizes the Special Master's evaluation of the "Smeeth article," the "Carty," study and the "Liuba article." The court notes, however, the Special Master fully addressed each study in his decision.

Regarding the "Smeeth article," petitioner argues

> Smeeth and other epidemiological studies fail to capture the **rare** adverse events post vaccination. This is, of course, why Petitioner is not required to support a theory of causation with epidemiological studies. The lack of statistical power makes them wholly useless when looking at vaccine-related rare events. The Smeeth authors reviewed the records of 20,486 patients, and this number lacks the statistical power to capture the type of event suffered by Mrs. Druery. Additionally, using population studies to argue that a vaccination does not harm "most people" still fails to take individuals like Mrs. Druery into account—namely, individuals with pre-existing vasospastic conditions who may be particularly sensitive to proinflammatory cytokine release after vaccination. While Smeeth ultimately concluded that it did not find an "increased statistical risk" of a cardiovascular event following influenza vaccination, that does not answer the causation question at all. Even with the small statistical power, **there were 77 people who suffered a myocardial infarction within 1-3 days of the influenza vaccination in the Smeeth study, and 171 people who suffered a myocardial infarction within 1-7 days of influenza vaccination**. Out of only 20,486 total people, that is a significant number of heart attacks in close proximity to vaccination, and yet no effort was made by the authors to look at causation of these individuals' cardiac events.

(emphasis in original). Special Master Horner, however, in his decision found:

> The reasons for this cardioprotective effect are not entirely clear, but may have to do simply with the ability of the flu vaccine to prevent infections, which are themselves associated with cardiovascular events. This likely leads to a statistical reduction in cardiovascular events. That does not in itself mean the flu vaccine is incapable of causing acute cardiac events such as myocardial infarction. However, it does mean that the inflammatory

> response to vaccination cannot be merely equated in its cardiovascular effects with infection. For example, Smeeth, et al., a study discussed by both parties' experts, examined 20,486 individuals that suffered myocardial infarction and 19,063 patients experiencing stroke to study whether the 90-day period following any inflammatory event (infection or vaccination) represented an elevated risk of cardiovascular adverse effect. The study detected the risk of myocardial infarction and stroke following infection, but found no elevated risk following vaccination. (Smeeth, et al.) In a smaller prospective study of optimally treated coronary artery disease patients comparing 325 vaccinees against 333 patients administered a placebo, major adverse cardiac events (including myocardial infarction) occurred less often in the vaccinated group.

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *16 (internal references omitted).

Petitioner also alleges in the Motion for Review:

> Contrary to the Special Master's contentions, the medical literature provides more than adequate support and cannot be ignored. **Carty discusses an acute immune response**, which is exactly what Mrs. Druery had. In Carty et al., the authors measured the levels of IL-6 (a pro-inflammatory cytokine), CRP [c-reactive protein], and SAA (Serum amyloid A) in participants both with and without severe coronary artery disease ("CAAD") at the baseline time point and the time point of 24 hours after vaccination. The subjects received the influenza vaccination, and the authors reported that "[t]he postvaccination levels of all markers **were significantly higher** than baseline levels for both men with CAAD . . . and for men without CAAD." (emphasis added). Glaser et al. is another article that demonstrates the production of cytokines post-vaccination and supports Petitioner's theory of causation. The Liuba article stands for the proposition that abnormalities in arterial function persist after the flu shot. This is exactly what happened to Mrs. Druery.

(emphasis; second alteration and omission in original; internal references omitted). The Special Master also specifically addressed the Carty study and the Liuba article. In his analysis of Althen prong 1, Special Master Horner determined:

> [t]he four articles cited by Dr. Stark are inadequate to support his contention that the flu vaccine can cause myocardial infarction. Carty et al. examined inflammatory markers in 43 men with severe carotid artery disease and 61 men without. (Carty, et al.) They found "mild, but measurable" acute phase responses among both groups. Markers for CRP, IL-6, and serum amyloid-a (SSA) were higher in those with disease, but only significantly so for SSA. The authors did not report on adverse events and concluded only that acute phase response variability may be predictive of underlying vascular disease. Liuba et al. found that endothelial abnormalities in human

> vasculature can persist for up to two weeks following a flu vaccination; however, given the size of the study and limited follow up, the authors disclaimed any insight into the significance of this finding, noting instead that prior studies have shown the flu vaccine to be cardioprotective. (Liuba, et al.) Glaser et al. found that patients with depressive symptoms may experience a stronger inflammatory response to vaccination with no indication the difference would affect cardiovascular health. (Glaser, et al.) Ritter et al. is a single case report of a woman who experienced vasculitis and myocardial infarction following a flu vaccine. (Ritter, et al.) However, Dr. LaRue stresses that the subject's vasculitis distinguishes the case report from this case.

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *17 (footnote and internal references omitted; alteration added). Regarding Dr. LaRue, referenced by Special Master Horner at the end of the quotation above, and Dr. LaRue's interpretation of the articles cited by petitioner, Special Master Horner noted:

> Dr. LaRue stresses that "[t]here is currently no scientific evidence of any relationship between influenza vaccine and myocardial infarction or ventricular arrhythmia. [sic[20]] He stresses that systematic review has shown the safety of the flu vaccine. Additionally, studies have specifically shown that the flu vaccine is associated with lower rates of cardiovascular morbidity and mortality. In particular, Dr. LaRue notes a study that compared the risk of myocardial infarction and stroke following influenza vaccination and systemic infection. The study found subjects had no increased risk of myocardial infarction for up to 91 days post-flu vaccination. Dr. LaRue stresses that the Carty, Glaser, and Luibo [sic] studies cited by Dr. Stark have no evidence to indicate that the observation of elevated cytokines was clinically meaningful. In contrast, he cites a study by Posthouwer, et al., which found that post-vaccination inflammation, measured by CRP, did not increase clotting ability. Dr. LaRue notes that the Ritter case report involved an injury different than what this petitioner experienced.

Id. at *13 (first alteration in original; internal references and footnotes omitted).

The Special Master did not only address the four articles cited by Dr. Stark, but Special Master Horner additionally addressed the references by Dr. Axelrod, another expert retained by petitioner. Special Master Horner determined in his decision:

> Dr. Axelrod cites some of the same literature as Dr. Stark (most notably Liuba, et al.), but also more specifically seeks to bridge the remaining gap between vaccine cytokine response and cardiovascular injury by discussing

[20] The quotation from Dr. LaRue's expert report ends after the words "ventricular arrhythmia."

vasospasms. Dr. LaRue agrees that coronary artery vasospasm is a potential cause of MINOCA. However, the purported link to vaccination remains unpersuasive.

Dr. Axelrod relies in significant part on literature measuring cytokine levels relative to vasospasm in the context of subarachnoid hemorrhage, most notably a study by Rasmussen, et al. (citing Rasmussen, et al.) However, Dr. Levinson questions whether this is a relevant context for assessing coronary artery spasm. Dr. Levinson's concern is especially well taken when comparing the Rasmussen study against the Fassbender study, a separate study cited by Dr. Axelrod regarding subarachnoid hemorrhage. (Fassbender, et al.) The Fassbender study examined several cytokines, including IL-6 and TNF-α, using cerebral spinal fluid. These cytokines were elevated among subarachnoid hemorrhage patients when measured this way and were correlated with cerebral vascular complications. The authors explained that in the context of subarachnoid hemorrhage, the excessive inflammatory response originates in and is "compartmentalized" to the spine and subarachnoid space, specifically affecting the cerebral vasculature. Moreover, although the manner by which cytokines contribute to cerebral vasospasms is not entirely clear, the current hypotheses include explanations that relate to specific features of the cerebral arteries. In contrast, the Rasmussen study examined plasma cytokine levels as measured from peripheral blood samples. In pertinent part, that study found no association between vasospasms and either IL-6 or TNF-α. (Rasumussen [sic], et al.) Thus, comparison between the Fassbender and Rasmussen studies suggests that what is true of cytokines within the central nervous system and cerebral vasculature is not necessarily true of cytokines circulating peripherally as measured from blood samples, leaving these studies far less persuasive with respect to what would affect the coronary arteries.

Dr. Axelrod stresses the Rasmussen study because it shows elevated cytokines associated with subarachnoid hemorrhage that are ultimately lower than what was observed post-vaccination in an unrelated study by Kashiwagi, et al. (citing Kashiwagi, et al.) Dr. Axelrod's comparison of the cytokine levels measured in Rasmussen to the post-vaccination cytokine levels observed in Kashiwagi is unpersuasive given that none of the cytokines measured in Kashiwagi were associated with vasospasm in the Rasmussen study. Dr. Axelrod's theory ultimately relates to vasospasm, not subarachnoid hemorrhage, and Dr. Axelrod has not substantiated that subarachnoid hemorrhage is of any relevance in itself. Nor did Kashiwagi, et al., examine cardiovascular events. Li, et al., does discuss elevated Il-6 and CRP as a marker among patients with variant angina. (Li, et al.) However, Dr. Levinson stresses that it does not evidence these markers as being causes of vasospastic events. To the extent the authors hypothesize

> inflammation as a contributor to variant angina, they conclude it may be a chronic factor. (Li, et al.)
>
> Dr. Axelrod additionally cites the Bowman study, in which vasospasm of the femoral artery was induced by IL-6 in rats and the Gardiner study, in which TNF-α and IL-1β were used to invoke cardiovascular response in rats; however, these studies are not persuasive given Dr. Axelrod's specific reliance on Rasmussen, et al. Regardless of what the rat models showed, Rasmussen found no association between either IL-6 or TNF-α and vasospasm in humans. (Rasumussen [sic], et al.) Even setting the Rasmussen study aside, it is still not clear that these rat studies are reasonably similar to what petitioner's experts theorize happened in this case. Of note, the Bowman authors explain, consistent with the above, that their model is intended to mimic cerebral vasospasm and that human studies have reached inconsistent results with respect to whether cytokines contribute to subarachnoid hemorrhage. (Bowman, et al.).

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *18–19 (emphasis in original; alteration added; internal references omitted).

> In the Motion for Review petitioner argues:
>
> Dr. Axelrod, Petitioner's expert immunologist, discusses vasospasm related to the elevation of cytokines post-vaccination. However, the Special Master criticizes this theory as "Dr. Axelrod relies in significant part on literature measuring cytokine levels relative to vasospasm in the context of subarachnoid hemorrhage . . ." As explained in his expert report, Dr. Axelrod is citing to articles like Fassbender to demonstrate that "[c]oncentrations of IL-6 associated with a poor outcome. Vasospasm is associated with increased cerebral blood flow velocities (the velocity increases with narrowing of the blood vessel (vasospasm). They found that the vasospasm associated with increased levels of Il-6." Petitioner's experts are allowed to extrapolate from a condition causing vasospasm (like subarachnoid hemorrhage) to Petitioner's injury.

(alterations and omissions in original; internal references omitted). Petitioner's experts, and specifically Dr. Axelrod, were "allowed to extrapolate from a condition causing vasospasm (like subarachnoid hemorrhage) to Petitioner's injury," but Special Master Horner did not believe petitioner's experts had demonstrated the necessary link between acute cardiac events and an influenza vaccine.

Petitioner also argues that "[i]t is impossible to find a study perfectly tailored to Mrs. Druery's injury, as individuals who suffer myocardial infarction after vaccination likely are not undergoing bloodwork for cytokine levels to be included in medical literature." (alteration added). Special Master Horner, however, did not require a "study perfectly tailored to Mrs. Druery's injury," but did require petitioner to put forth sufficient evidence

to demonstrate that the influenza can cause acute cardiac events. Special Master Horner, when reviewing the medical literature cited by petitioner's experts, determined that the petitioner was unable to prove such a link. See W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d at 1356 ("the petitioner must do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence" (quoting Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d at 1322)).

Special Master Horner also weighed the respondent's experts' opinions in reaching his conclusions under Althen prong 1. For example, addressing respondent's expert Dr. Rose, Special Master's decision recognized

> Dr. Rose's written opinion stresses that epidemiology has not only failed to detect any association between the flu vaccine and heart disease, but studies have also found that vaccination can actually diminish the severity of heart disease and it is now common clinical practice to recommend the flu vaccine for cardiac patients at risk of enhanced disease. Dr. Rose stresses that the flu vaccine, in particular, does not utilize an adjuvant to boost the immune response to vaccination. According to Dr. Rose, petitioner's post-vaccination symptoms are attributable to a local inflammatory response rather than a systemic inflammatory response, with no systemic inflammation being evident.

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *14 (internal references and footnotes omitted).

For respondent's expert Dr. LaRue, Special Master Horner summarized Dr. LaRue's opinion as follows:

> Dr. LaRue opines that petitioner's cardiac event is best described as myocardial infarction with no obstructive coronary atherosclerosis ("MINOCA"). This is a syndrome characterized by clinical evidence of myocardial infarction with normal or near-normal coronary arteries. Causes of MINOCA include coronary artery vasospasm, eccentric coronary plaque, Takotsubo syndrome, microvascular spasms, myocarditis, and coronary embolism. Of these causes, Dr. LaRue finds eccentric coronary plaque (with positive remodeling) or Takotsubo syndrome to be more likely. Petitioner fits the profile for Takotsubo syndrome in several ways and it is associated with migraine headaches; however, although it remains a "reasonable possibility," it is less likely because petitioner's cardiac MRI demonstrated a transmural infarct localized to the ALD [Adrenoleukodystrophy[21]] territory

[21] Adrenoleukodystrophy is defined as "a rare demyelinating disease of the central nervous system that is inherited as a sex-linked recessive trait chiefly affecting males in childhood and that is characterized by progressive blindness, deafness, tonic spasms, and mental deterioration."

> and she had substantial troponin elevation, higher than would typically be seen with Takotsubo syndrome. Thus, Dr. LaRue opines that the most likely explanation for petitioner's MINOCA is positive remodeling (eccentric plaque disruption). He explains that "[t]his clinical entity can present with chest pain, ST segment elevation on ECG, elevated troponin values, and no obstructive disease visible on coronary angiography. Additionally, patients with [myocardial infarction] related to no obstructive coronary atherosclerosis can demonstrate ischemia and infarction on cardiac MRI, as was the case for [petitioner]." Petitioner's ventricular fibrillation arrest was a result of her MINOCA.

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *12 (first alteration and footnote added; internal references omitted).

Despite the petitioner's misgivings about Special Master Horner's interpretation of the articles provided to the Special Master by the petitioner, the court finds that Special Master Horner gave careful consideration to the articles and studies referenced by petitioner's experts. His factual findings based on the record before him, including his analysis of the submitted articles, were not arbitrary or capricious. Nor can the court conclude that Special Master Horner's conclusions regarding Althen prong 1: "Considering all of this collectively and in the context of the record as a whole, I conclude that petitioner has not preponderantly established that the flu vaccine can cause acute cardiac events, including myocardial infarction," Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *19, was an abuse of discretion or not in accordance with law. As explained by the Federal Circuit:

> With regard to both fact-findings and fact-based conclusions, the key decision maker in the first instance is the special master. The Claims Court owes these findings and conclusions by the special master great deference—no change may be made absent first a determination that the special master was "arbitrary and capricious."

Munn v. Sec'y of Health & Hum. Servs., 970 F.2d at 870; see also 42 U.S.C. § 300aa-12(e)(2)(B). The court, therefore, will not disturb the Special Master's conclusion that petitioner did not meet her burden of proof on Althen prong 1.

Althen Prong 2

As reflected above, because a petitioner must meet all three Althen prongs, Special Master Horner was not obligated to evaluate the Althen prong 2 or Althen prong 3 after determining petitioner did not meet her burden of proof on Althen prong 1. See W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d at 1358 ("Because a petitioner must establish 'all three prongs of the Althen test,' id. [de Bazan v. Sec'y of Health & Hum.

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https://www.merriam-webster.com/dictionary/adrenoleukodystrophy (last visited Feb. 29, 2024).

Servs., 539 F.3d at 1352], it was not necessary for the special master to evaluate whether Petitioner established a medical theory as required by Althen prong one." (alteration added); O.M.V. v. Sec'y of Health & Hum. Servs., 157 Fed. Cl. at 389 (quoting DePena v. Sec'y of Health & Hum. Servs., 133 Fed. Cl. 535, 549 (2017) ("'[A] petitioner must satisfy all three prongs of the Althen test; a failure to satisfy one prong is fatal to the case.'") (alteration in original); see also Dennington v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 640, 652 (2023) ("Accordingly, in order to successfully challenge the Chief Special Master's determination, Petitioner must demonstrate that the Chief Special Master's decision was arbitrary, capricious, or otherwise not in accordance with law with regard to all three prongs of the Althen test. See 42 U.S.C. § 300aa–12(e)(2)(B). Because the Court determines that Petitioner fails to demonstrate that the Chief Special Master's determination with regard to Althen prong one was in error, the Court must deny her motion for review.").[22] Special Master Horner, however, did continue his analysis regarding Althen prong 2, ultimately concluding: "I find that petitioner has not met her burden under Althen prong two of preponderantly establishing a logical sequence of cause and effect demonstrating that her flu vaccine did cause her injury." Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *22.

Petitioner argues that "[t]he Special Master's minimization of the opinions of Mrs. Druery's treaters is arbitrary and capricious as he erroneously elevates the burden of proof Mrs. Druery must satisfy under Althen Prong 2." (alteration added). Petitioner contends:

> **Treating physicians clearly expressed their opinion that Mrs. Druery's injury is vaccine related**. Yet the Special Master states, "I have considered the views of petitioner's treating physicians, but do not find that any of the treating physician statements meaningfully support vaccine causation." This is contrary to law, and simply a [sic] unsupportable conclusion. The Special Master has placed an impossible burden upon Mrs. Druery, and it is unclear what language from a treating physician would satisfy the Special Master's erroneously elevated standards. Of course, if the Special Master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate. Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1363 (Fed. Cir. 2012). With all due respect to Special Master Horner, his construction of the opinions of the treating physicians in this case is both implausible and legal gymnastics.

[22] In a footnote, the Judge of the United States Court of Federal Claims in Dennington noted: "Given this finding regarding prong one, the Court need not address Plaintiff's arguments regarding prongs two and three of the Althen test." Dennington v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. at 652 n.5. Just as Special Master Horner nevertheless considered the additional Althen prongs in his analysis, this court likewise addresses the petitioner's arguments in the Motion for Review for prong 2 of the Althen test.

(emphasis in original; alteration added; internal reference omitted). Respondent contends: "While petitioner clearly disagrees with the Special Master's findings, that is not grounds to disturb his conclusion that the flu vaccine did not cause her MI, where his findings are amply supported by the record." (alteration added).

Petitioner, before this court, argues: "Dr. Miller, one of Petitioner's cardiologists, states '[i]t is very likely that her cardiac event in 2016 was Takotsubo syndrome, however her wall motion appears to have not recovered. The precipitating event is unclear, **however appears to be related to the influenza vaccine**.'" (emphasis and alteration in original). Special Master Horner's decision noted that "[w]ithin the petition, she acknowledged that her medical records are unclear with respect to a specific diagnosis for her acute cardiovascular event." Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *2 (alteration added).[23] Further, regarding Dr. Miller and petitioner's other treating doctors, the Special Master determined:

> I have considered the views of petitioner's treating physicians, but do not find that any of the treating physician statements meaningfully support vaccine causation. Petitioner stresses that her physicians did not reach any alternative conclusion regarding the cause of her cardiac event and, in fact, opined that it was vaccine-caused. In particular, petitioner quotes the following by Dr. Miller, petitioner's treating cardiologist: "[i]it is very likely that her cardiac event in 2016 was Takotsubo syndrome, however her wall motion appears to have not recovered. The precipitating event is unclear, however appears to be related to the influenza vaccine."
>
> Dr. Miller's statement is not consistent with petitioner's claim given that it is premised on his acceptance that petitioner's history very likely constituted Takotsubo syndrome. Her experts, by contrast, did not support such a view. Neither Dr. Stark nor Dr. Axelrod discussed Takotsubo syndrome as any part of their causal opinion. Dr. Morgan did indicate that Takotsubo syndrome can result from systemic inflammation, but this was not substantiated. Moreover, Dr. LaRue indicates that his review of the medical literature refutes that assertion. In any event, Dr. Morgan opined that petitioner did not suffer Takotsubo syndrome. Without additional expert support, Dr. Miller's statement is inadequate standing alone to substantiate

[23] In response to this statement, petitioner argues in the Motion for Review:

> What the Petition actually states is "As the Court and Respondent will see, Ms. Druery's medical chart is somewhat confusing as to her actual diagnosis. At some points, it is referred to as an acute MI. In other parts, she is diagnosed with myocarditis and/or pericarditis." Petition, ¶ 13. This is true. What Petitioner is describing is her treating physicians worked through multiple diagnoses and conducted extensive testing to figure out why a healthy woman suffered an acute MI.

> that the flu vaccine could reasonably be considered a precipitant of Takotsubo syndrome.
>
> Moreover, considering the quotation from Dr. Miller as a whole, it is best interpreted as raising only a suspicion of vaccine causation. That is, prefaced with the caveat that the precipitating event is "unclear," use of the word "appears" falls short of stating a conclusion. Indeed, petitioner acknowledges that "[t]his statement from a treating physician is basically indicating that we may never know for sure what happened to [petitioner]" but argues that it is an assertion that "based on the clinical presentation, the timing after immunization, and the lack of other precipitating events, it was probably the shot." However, the Federal Circuit has explained that "[a]lthough probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." Althen [v. Sec'y of Health & Hum. Servs.], 418 F.3d at 1278 (citing Grant [v. Sec'y of Health & Hum. Servs.], 956 F.2d at 1149).

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *21 (first three alterations in original; footnote omitted). Petitioner argues that "Mrs. Druery's injury does not perfectly match the criteria of Takotsubo syndrome, but the cardiologist's statement that he found the overall injury to be likely vaccine-related was ignored," and "Dr. Miller also does not fully commit to this diagnosis. However, Dr. Miller clearly states that he believes what happened to Mrs. Druery to be vaccine-related." Petitioner continues: "**Furthermore, Dr. Miller is not even fully committed to Takotsubo syndrome as the diagnosis**. Like any good treating physician does, Dr. Miller simply thinks through a potential differential diagnosis, and there is no legal basis for holding this against Mrs. Druery." (emphasis in original).

Although the petitioner strenuously disagrees with Special Master Horner's interpretation of Dr. Miller's diagnosis, as the United States Court of Appeals for the Federal Circuit has explained the reviewing courts "'do not sit to reweigh the evidence. [If] the special master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious.'" Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs., 717 F.3d at 1367 (modification in original) (quoting Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d at 1363). The court finds Special Master Horner's interpretation of Dr. Miller's statements to be plausible.

Additionally, Special Master Horner identified other statements in the record before the Special Master explaining:

> I have also considered the other treating physician statements contained in petitioner's medical records. In 2018, petitioner received a vaccine exemption from a physician's assistant in Dr. Lewis's office; however, the

> statement indicates only vaguely that her vaccine reaction "affected her heart." This is especially unpersuasive given the cardiologist's explicit conclusion that the precipitating event is unclear. Other statements within the medical records document the fact of petitioner having experienced a post-vaccination reaction without linking that reaction to petitioner's cardiac condition. For example, her November 1, 2016, discharge includes "[status post] flu shot reaction" without any indication it was causally related to any of the other listed diagnoses. Dr. Orlovic and Dr. Mateo-Bilbeau both recorded the history of vaccine reaction without assessing it as causally related. Several other records are limited to merely recording petitioner's own assertion that her cardiac event was due to her flu vaccination.

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *21 (internal references and footnote omitted; alteration in original). Petitioner takes issue with the weight the Special Master gives as to the petitioner having received a vaccine exemption from a physician's assistant in Dr. Lewis's office in 2018. As noted above, according to the Special Master, "the statement indicates only vaguely that her vaccine reaction 'affected her heart.'" Petitioner argues:

> **This is clear, not vague. The vaccine affected her heart**, **which is the alleged injury herein**. This is the treating cardiologist ordering no further influenza vaccination because of the MI event she suffered after the last shot she received. It is the treating doctor stating that further influenza vaccination is medically contraindicated.

(emphasis in original). Petitioner also emphasizes that "testimony from treating physicians is incredibly important and elucidating for proving causation." Special Master Horner considered the statements from the treating physicians, but after weighing the value of the statements, ultimately concluded the testimony was insufficient to meet the burden of showing actual causation.

Additionally Special Master Horner considered the health of the petitioner before her vaccine and any symptoms after the vaccination was administrated, and how both petitioner's and respondent's experts viewed petitioner's medical history. In his decision, the Special Master wrote:

> Petitioner stresses in her brief that she did not have a history of heart disease or heart attack, quoting Dr. Stark's assessment that she was a woman "in excellent health, with a history of occasional migraine headaches" as well as Dr. Glickman's October 26, 2016, assessment of "no cardiac pulmonary GI or GU symptoms." Petitioner implies that, but for her proposed explanation of events, her condition would otherwise be mysterious or unlikely. Importantly, however, petitioner did have several risk factors for an acute cardiovascular event. Both Dr. Morgan for petitioner and Dr. LaRue for respondent agree that petitioner's atherosclerosis of the small diagonal artery is significant to assessing her condition even though it is not directly implicated in her myocardial infarction. Specifically, they both opine

> that the fact of this finding makes it more likely that petitioner's myocardial infarction could have been caused by an undetected clot or plaque. Additionally, petitioner also had a documented history of hypertension, which is a risk factor for atherosclerosis. Further to this, petitioner's immunology expert, Dr. Axelrod, has filed review articles indicating that migraine disorders are considered an overall risk factor for cardiovascular disease. While petitioner asserts this supports her claim because migraine disorders show a predisposition to vasospasm, the literature cited by Dr. Axelrod confirms the reason for the association between migraines and cardiovascular events is unknown. Thus, the evidence regarding migraines is sufficient only to establish that petitioner was statistically at risk for cardiovascular disease as a general matter, i.e., this was a risk factor regardless of what petitioner theorizes.
>
> Petitioner also stresses the symptoms she experienced soon after vaccination, including swelling, hives, headache, arm pain, and malaise. The fact of these symptoms is not reasonably contested. However, because Drs. Stark and Axelrod were not persuasive in establishing that post-vaccination inflammation is clinically meaningful to myocardial infarction, the fact that petitioner suffered constitutional symptoms following her vaccination is of diminished significance. Respondent's experts persuasively opined that, although technically systemic as petitioner contends, these symptoms are representative only of mild inflammation. As Dr. Levinson stressed, these symptoms commonly occur in healthy vaccinees and they are not established as a precursor to adverse cardiac events.

Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *19–20 (internal references omitted). Therefore, as indicated above, Special Master Horner concluded: "For all these reasons, I find that petitioner has not met her burden under Althen prong two of preponderantly establishing a logical sequence of cause and effect demonstrating that her flu vaccine did cause her injury." Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *22.

As under Althen prong 1, the court finds that, regarding Althen prong 2, the Special Master adequately considered the petitioner's medical records, including those of petitioner's treating physicians, and the views of the parties' respective experts. Therefore, the court finds that Special Master Horner's factual findings based on the medical record before him were not arbitrary or capricious, and, therefore, the court defers to the findings of the Special Master that the petitioner was not able to establish a logical sequence of cause and effect demonstrating that petitioner's vaccine caused her injury. See Munn v. Sec'y of Health & Hum. Servs., 970 F.2d at 870.

Althen Prong 3

As noted above, regarding Althen prong 3, Special Master Horner concluded because "Althen prong three coincides with Althen prong one, petitioner's inability to meet her burden under prong one effectively precludes her from being able to meet her burden under Althen prong three. Even assuming that petitioner satisfied Althen prong three, that alone would not satisfy petitioner's overall burden of proof." Druery v. Sec'y of Health & Hum. Servs., 2023 WL 5094088, at *22.[24] Moreover, petitioner did not challenge Special Master Horner's conclusions regarding Althen prong 3 in petitioner's Motion for Review. Therefore, Special Master Horner's determination regarding Althen prong 3 is not further addressed in this Opinion.

Petitioner's Burden of Proof Concerns

As noted above, in the Motion for Review, petitioner argued:

> To state that Petitioner did not meet her burden of proof with this level of treating physician and expert support is arbitrary and capricious, and contrary to law in terms of the burden of proof applicable to Petitioners in the Vaccine Program. Under this evidence, it was legal error for the Special Master to find a failure of Petitioner to meet her burden. There is little more a Petitioner can do in a Vaccine Program case to meet her burden than the evidence here.

Petitioner's counsel also argued in the Motion for Review that

> to say that the Petitioner in this case - with these facts - failed to meet her burden of proof in the Vaccine Program is not in accordance with the law. It is a misapplication of the burdens in the Vaccine Program and worse, it is

[24] As noted above, to establish causation in fact for a Non-Table claim, such as petitioner's claim in the above captioned case, a petitioner must satisfy all three of the elements established by the United States Court of Appeals for the Federal Circuit in Althen v. Secretary of Health & Human Services, 418 F.3d at 1278. See Sanchez v. Sec'y of Health & Hum. Servs., 34 F.4th at 1353; see also Andreu ex rel. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d at 1374–75 (quoting Althen v. Sec'y of Health & Hum. Servs, 418 F.3d at 1278) ("In Althen, we set forth a three-prong test for establishing causation in fact: 'Concisely stated, [a claimant's] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. If [a claimant] satisfies this burden, she is entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.'") (alterations in original).

> cloaking a dismissal of a compensable vaccine claim under language that the Special Master feels will survive appeal.

At the oral argument, petitioner's counsel argued that the "burden of proof should be on the government now to demonstrate a more likely alternative explanation than vaccination. And I can tell you right now, there is not one, but that process never happened at the Vaccine Program level." In response, the court asked petitioner's counsel whether there are any prior vaccine cases which addressed how to handle the burden of proof shift put forth by petitioner's counsel. Petitioner's counsel admitted he could not identify a specific case, and further acknowledged at the oral argument "most of that issue is discretionary with special masters," but added, "there are cases where the evidence is overwhelming, and because -- and it doesn't even have to be overwhelming, it just has to be evidence that checks all the Althen boxes and demonstrates that the petitioner satisfied their threshold burden. That is a systemic problem with the special masters." Petitioner's counsel continued:

> Again, if you switch the burden to the government, maybe they can prove a more likely explanation, but under facts like that, and facts like we have in this case, you can't just shrug it off and say that we didn't meet our burden. I do not believe that's what Congress intended when they created the Vaccine Act in the first place, and I don't think that's how this program is supposed to work. I apologize, I can't give you a specific case cite beyond that.

Although the petitioner's counsel zealously advocated for his client, and the court understands the frustration expressed by petitioner's counsel, as a member of the petitioners' bar, about decisions from Special Masters that determine that petitioners have not met their initial burden of proof, the court recognizes that the Special Masters have discretion, especially how to evaluate the respective expert reports submitted as well as the submitted medical records. See Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d at 1381 ("We do not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." (citing Porter v. Sec'y of Health & Hum. Servs., 663 F.3d at 1249).

Recently the United States Court of Appeals for the Federal Circuit issued a decision in Winkler v. Secretary of Health & Human Services. See Winkler v. Sec'y of Health & Hum. Servs., 88 F.4th 958. Mr. Winkler sought compensation for an off-Table injury of the development of Guillain-Barré Syndrome (GSB) following a Tdap (Tetanus, Diphtheria, and Pertussis) vaccination. See id. at *1. Although for a different administrated vaccine and a different injury than suffered by the petitioner in the above captioned case, the issue of discretion that frustrated petitioner and petitioner's counsel in the above captioned case is also present in the Federal Circuit's decision in Winkler. In Winkler, the Special Master denied his claim, and

> [i]n evaluating Winkler's claim for relief, the Special Master made separate holdings for each Althen prong. First, she assumed that Winkler had established the first prong, without fully evaluating whether he had in fact

> done so. Special Master Decision [Winkler v. Sec'y of Health & Hum. Servs., No. 18-203V, 2021 WL 6276203, at *2 (Fed. Cl. Dec. 10, 2021), aff'd, No. 18-203V, 2022 WL 1528779 (Fed. Cl. May 13, 2022), aff'd, 88 F.4th 958 (Fed. Cir. 2023)] at *23. She then held that he had not established the second prong but had established the third. Id. at *23–26. She subsequently denied relief because of a failure to show, by preponderant evidence, that the Tdap vaccine was the reason for Winkler's GBS. Id. at *26.
>
> In reaching her conclusion on the second Althen prong, the Special Master thoroughly reviewed evidence relating to Winklers May 3, 2017 visit to his physician during which he was diagnosed with gastroenteritis. See Special Master Decision at *23–25. Although the physician did not probe further to determine whether or not the gastroenteritis was due to a gastrointestinal infection, expert testimony submitted on behalf of the government supported a conclusion that Winkler likely suffered from such an infection. Id. at *24. In particular, a medical expert testifying on behalf of the government reviewed Winkler's complaints of "fatigue, bloody stools, chills, and feeling feverish" and found that that particular constellation of symptoms was consistent with a *C. jejuni* infection.[[25]] Id. at *20, *24. The Special Master thus considered two potential triggers of the GBS: the Tdap vaccine and the diarrheal illness that was consistent with a *C. jejuni* infection.

Winkler v. Sec'y of Health & Hum. Servs., 88 F.4th at 962 (alterations and footnote added). On appeal to the United States Court of Appeals for the Federal Circuit, Mr. Winkler argued that

> the Special Master erred by requiring him to disprove that he suffered from a *C. jejuni* infection. Pet. Br. at 6. However, Winkler mischaracterizes the burden that he was required to meet. In asserting an off-Table injury, Winkler needed to show, by preponderant evidence, that his Tdap vaccination was a substantial factor in causing his GBS. He did not need to show that he did not suffer from a gastrointestinal infection, or that said gastrointestinal infection did not contribute to his GBS. Nor did he have to show that the Tdap vaccination was the only cause of his GBS. The Special Master made that clear, explaining that "petitioner is not required to eliminate other potential causes in order to be entitled to compensation." Special Master Decision at *25 (citing Walther v. Sec'y of Health & Hum. Servs., 485 F.3d 1146, 1149–52 (Fed. Cir. 2007)). Here, the Special Master did not conclude that Winkler was not entitled to relief because he did not disprove evidence of an infection. Rather, the Special Master held that

[25] C. jejuni or Campylobacter jejuni refers to "any of a genus *(*Campylobacter*)* of spirally curved motile gram-negative rod-shaped bacteria of which some are pathogenic in domestic animals and humans."
https://www.merriam-webster.com/dictionary/campylobacter (last visited Feb. 29, 2024).

> Winkler was not entitled to relief because he did not establish a prima facie case of causation of his GBS by the Tdap vaccine. As explained in Doe v. Secretary of Health and Human Services, a "petitioner's failure to meet his burden of proof as to the cause of an injury or condition is different from a requirement that he affirmatively disprove an alternative cause." 601 F.3d 1349, 1356–58 (Fed. Cir. 2010) (discussing 42 U.S.C. § 300aa-13(a)(1)).
>
> Winkler further argues that the Special Master erred in failing to make a factual finding as to whether or not he actually suffered from a *C. jejuni* infection. Pet. Br. at 6. He also contends that, without said factual finding, it was error for the Special Master to consider "irrelevant evidence" of a *C. jejuni* infection. Id. We disagree. As set forth in Stone v. Secretary of Health and Human Services, "evidence of other *possible* sources of injury can be relevant . . . to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question." 676 F.3d 1373, 1379 (Fed. Cir. 2012) (emphasis added). There is no dispute that Winkler's diarrheal illness was a possible source of injury. Indeed, an expert testifying on Winkler's behalf acknowledged that "it is not possible to distinguish whether . . . the diarrheal illness alone was responsible for [the] GBS." Special Master Decision at *24. Nor is there a dispute that the diarrheal illness could have been due to a *C. jejuni* infection and that such an infection could have caused Winkler's GBS. Id. at *10, *12–13. Especially given that lack of dispute regarding *C. jejuni* as a possible source of injury, evaluating the strength of Winkler's prima facie case did not require an explicit finding that Winkler actually suffered from a *C. jejuni* infection. The Special Master was free to consider evidence relating to whether or not Winkler suffered from a *C. jejuni* infection, as well as the likelihood that said infection triggered Winkler's GBS. Such contemplation of a potential causative agent when evaluating whether or not a petitioner has established a prima facie case is in accordance with the law.

Winkler v. Sec'y of Health & Hum. Servs., 88 F.4th at 962-63 (omissions in original).

Much like this court's analysis of the discretion attributed to Special Master Horner regarding his decision in Ms. Druery's case, the Federal Circuit explained the discretion afforded the Special Master in the Winkler case:

> To the extent that Winkler challenges the way in which the Special Master weighed evidence relating to *C. jejuni* infections in the absence of an express finding that he suffered from one, we find no abuse of discretion. "We do not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." Porter v. Sec'y of Health & Hum. Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1349 (Fed. Cir. 2010)). As explained in Hodges v. Secretary of Health and Human Services, "[t]hat level of deference is

> especially apt in a case in which the medical evidence of causation is in dispute." 9 F.3d 958, 961 (Fed. Cir. 1993). That makes reversible error and abuses of discretion "extremely difficult to demonstrate" when, as is the case here, the Special Master "considered the relevant evidence of record, dr[ew] plausible inferences and articulated a rational basis for the decision." Hines, 940 F.2d at 1528. Using that discretion, the Special Master found that Winkler "failed to provide preponderant evidence of a logical sequence of cause and effect required under Althen Prong Two." Special Master Decision at *25. We see no abuse of discretion in the Special Master's evaluation of the evidence that would mandate overturning her holding.
>
> Ultimately, while, based on the record before us, the Special Master could have gone either way, it was not arbitrary or capricious for her to conclude that Winkler did not prove his case. And the failure to prove an alternate cause does not obviate the need for proof of causation by the vaccine.

Winkler v. Sec'y of Health & Hum. Servs., 88 F.4th at 963 (alteration in original). The issue of discretion afforded the Special Masters are not unique to petitioner's case, and the Federal Circuit has made plain that when causation is an issue, "[t]hat makes reversible error and abuses of discretion 'extremely difficult to demonstrate.'" Id. (alteration added) (quoting Hines v. Sec'y of Health & Hum. Servs., 940 F.2d at 1528).

As determined above, in the specific case before this court on the petitioner's Motion for Review, Special Master Horner's specific evaluations and findings regarding petitioner's medical records, the submitted expert reports, the medical literature submitted, as well as the parties' filings, resulting in his conclusions, were not arbitrary or capricious based on the Vaccine Act and the developed, relevant case law. On that basis, this court sustains the determinations made by Special Master Horner in his decision.

CONCLUSION

For the reasons stated above, the court does not find that Special Master Horner arbitrarily or capriciously determined under Althen prong 1 that the petitioner did not establish that the flu vaccine can cause acute cardiac events. Nor does the court find that the Special Master arbitrarily or capriciously concluded under Althen prong 2 that petitioner did not establish a logical sequence of cause and effect demonstrating that petitioner's vaccine caused her injury. Therefore, Special Master Horner's decision is affirmed. Petitioner's Motion for Review is **DENIED**. The Clerk of the Court shall enter **JUDGMENT** consistent with this Opinion.

IT IS SO ORDERED.

s/Marian Blank Horn
MARIAN BLANK HORN
Judge